

MPhA News

Highlights from 2016
Pharmacists Month

Advocacy

Rx and the Law — Advocacy
Updates on National
Legislation and Policy

Editorial Article

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**Continuing Education
Article**

Addressing Barriers to
Optimal Health Care in the
Hispanic Community

Maryland Pharmacist

WINTER 2017

Advocacy Updates on National Legislation & Policy

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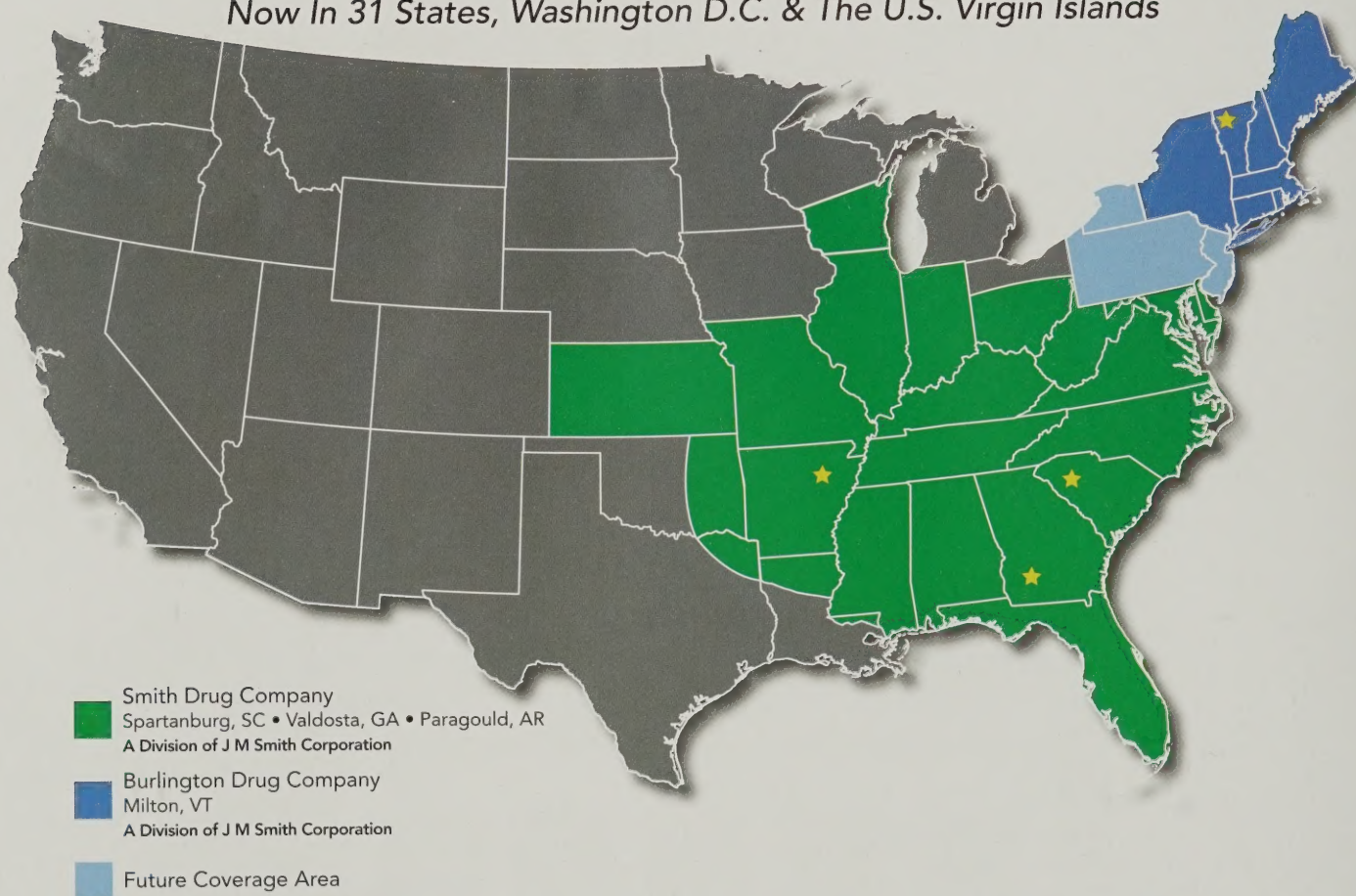


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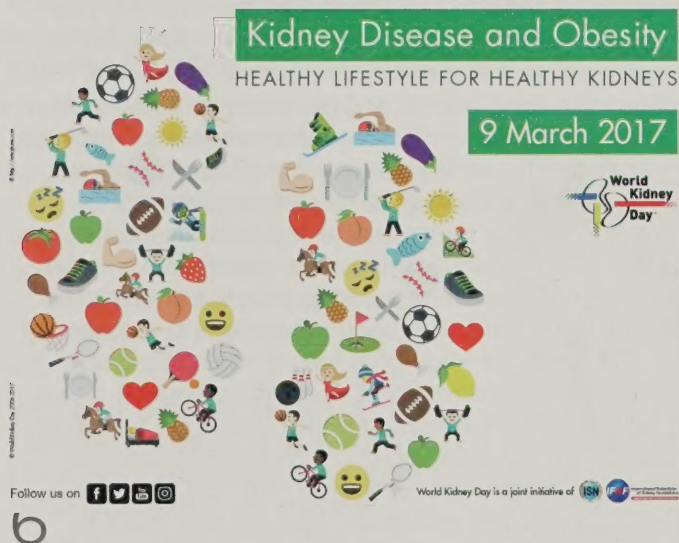
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This series, *Pharmacy and the Law*, is presented by Pharmacists Mutual Insurance Company and MPhA through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.



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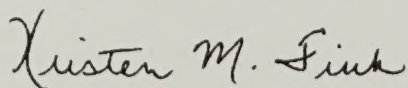
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MPhA has exciting things in store for you in 2017 including many opportunities to learn, advocate for our profession, and network with other pharmacy professionals throughout our state. We kicked off the 2017 CE events with our Annual Mid-Year Meeting on February 12th, which had CE for both our pharmacist and pharmacy technician members focusing on clinical updates, career development, and timely updates on issues impacting our profession. The legislative update held during the Mid-Year Meeting is just one of the events that we scheduled for you to easily learn how to impact pharmacy at the ground level as the laws are being written. On February 9th, we also hosted

an interactive advocacy workshop, which provided an in-depth opportunity for participants to role-play, actively learn techniques and tactics to engage legislators, and gain a better understanding of the legislative issues, just in time for Legislative Day on February 16th! If you have never been to Legislative Day, this was the year for you to participate! Hundreds of pharmacists and pharmacy students met in Annapolis to share pharmacy views with our legislators and make sure our voice is heard. Many legislators heard directly from their own constituents and get to know what issues are impacting the area they serve, so this is truly an instance where every voice matters. Pharmacy has been building momentum in our legislative efforts over the years and we have realized numerous successes including establishing collaborative practice, expanding vaccination authority and removing the proof of the English proficiency requirement for student pharmacists, just to name a few. We have also given information and testimony regarding numerous efforts with the potential to impact pharmacy interests, related to shrinking pharmacy networks and emergency refills, among many other issues. This year, we know that two of the items being discussed are pharmacists providing contraceptives, and student pharmacist intern requirements. MPhA has heard how important these legislative issues are to you and we see how they can directly impact our everyday practice. We have specifically engaged a lobbyist to help us take our forward momentum to the next level, but we cannot do it without you. We hope you will lend your expertise and voice to our legislative efforts and accompany us to Annapolis. If you are unable to come in person, write a letter or make a phone call to make sure that the pharmacy profession is represented, even a small effort is a step in the right direction. We are in the position to write our own story for our profession and we want to hear what issues are impacting your practice and what opportunities you see for growth.

Please feel free to email or call the office or come out to one of our upcoming events to talk in person and share your experience. We will have several CE dinners throughout the state this spring and several exciting events coming up at our headquarters. Keep an eye on the website and the Monday Message for upcoming events, and feel free to bring a pharmacy friend or two! I hope to see you there! ●



Kristen Fink, PharmD, BCPS, CDE
President

Rx and the Law

ADVOCACY

By Don. R. McGuire Jr., R.Ph., J.D.

*This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and MPhA through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.*

To paraphrase John Godfrey Saxe; *laws are like sausages, it's better not to see them being made.* I am not an expert on sausages, but I would disagree with this comment with regards to laws. Even if we don't get involved in the making of laws, we will be subject to them nonetheless. Pharmacists can ill afford to be impacted by laws drafted by those who know nothing about pharmacy.

Unfortunately for many of us, lobbying is a word with very negative connotations. It projects images of under the table dealings and improper exchanges of cash. So how do we inform lawmakers of the impact of proposed laws on the practice of pharmacy? Through advocacy.

Advocacy is simply the act of supporting a cause, an idea, or a proposed policy. Many state and national associations organize advocacy meetings for their members. While we can all do this individually, a group of concerned citizens visiting the lawmaker's office together can certainly make a larger impact. The purpose of these visits is to educate the lawmaker and their staff on proposed laws that impact our profession. We might be in favor of a proposal, opposed to it

or want to amend the language as presented.

Lawmakers are serving because they want to make a positive difference in our society. However, they are not experts in every field. There is only one pharmacist, Buddy Carter of Georgia, in the 114th Congress. The other Senators and Representatives need pharmacists' help to understand how proposals will affect pharmacy practice.

I have participated in advocacy meetings on both the state and national level. In my experience, the lawmakers and staffers are eager to hear how proposals will affect constituents in their districts. The meetings usually consist of an introduction, explanation of why you are there, what the real impact in their district will be, and what action you want them to take. For pharmacists, the potential impact is not always direct. The impact may be on our patients; denying access, increasing costs, or creating hurdles to care. Of course, these indirect impacts will have impact on your pharmacy practice. Many times the true impact on patients is not readily apparent. Pharmacists can explain how a particular policy will make it more difficult for

patients to get their medications. Don't expect immediate action. It is always a pleasant surprise to get a commitment, but many times the materials that you provide are circulated in the office before decisions are made.

Not all advocacy has to take place in Washington, D.C. or your state capital. Invite your lawmaker to visit your pharmacy while they are home in the district. Then they will get to see first-hand what you are doing for your patients, their constituents. You can also advise them about how proposed laws will impact your ability to provide these services. First-hand knowledge and stories of real impacts (not just theoretical ones) will have the most influence on the process.

If pharmacists don't educate lawmakers about the effects of the changes on their practices and their patients, who will? Don't think of it as lobbying. We are really educating our lawmakers. Joining and participating in professional organizations is a good way to get started. In the end, the profession will benefit and ultimately, our patients will too. ●

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

A Stepwise Guide to Planning and Implementing a “Healthy Kidneys” Event and Celebrating World Kidney Day

By Eugene Kwachuh, PharmD Candidate 2017 and Hoai-An Truong, PharmD, MPH, FNAP

The prevalence of chronic kidney disease (CKD), regardless of the stage in the adult population, was 14.8% in 2011–2014.^{1,2} The Centers for Disease Control and Prevention (CDC) states that about 10% of adults in the United States, which represents more than 20 million people, may have CKD.² Chances of developing CKD increases after age 50 and are most prevalent among adults older than 70 years.² One out of three adults with diabetes and one out of five adults with hypertension has CKD.² About 40% of individuals with CKD also have concomitant diabetes while 32% have hypertension and 40% have self-reported cardiovascular disease.¹ Besides these main risk factors, others include obesity, hypercholesterolemia, lupus as well as a family history of kidney disease. Most patients are asymptomatic during early stages and are often diagnosed at advanced stages. The highest increase in occurrence from 1999 to 2014 (5.45 to 6.6%) was observed in stage 3 cases.¹

The prevalence of self-reported CKD in the United States is low because kidney disease is often asymptomatic in the initial stages, which makes the need to screen and educate at risk populations, as well as performing medication therapy management vital. Adults with CKD have higher rates of premature death from all causes and are 16 to 40 times more likely to die than to reach end stage renal disease (ESRD).² CKD increases the chances of developing strokes, heart attacks and cardiovascular diseases. The CDC determined that the most efficient way to reduce personal suffering and associated costs of CKD is to prevent and treat its risk factors. Additionally, the Healthy People 2020 Initiative identified 14 objectives with focus on kidney disease, that highlights the necessity for an intervention.¹ The Center for the Advancement of Pharmacy Education (CAPE) educational outcomes⁴³ and the Standards and Guidelines of the Accreditation Council for Pharmacy Education (ACPE)³⁴ include domain and competency requirements in health promotion and wellness, and student organization initiatives also support active involvement of pharmacy students in public health activities. While the American Pharmacists Association Academy of Student Pharmacists (APhA-ASP)⁵ has initiatives for some important risk factors such as operations diabetes and heart, the Student National Pharmaceutical Association (SNPhA)'s Chronic Kidney Disease Initiative facilitates numerous activities to raise awareness on kidney disease throughout the year and could benefit from a guide to hosting an event.⁶ This article describes a step-by-step guide to planning and implementing a healthy kidneys education and outreach project for pharmacists, preceptors and students, based on the assessment, policy development, and the assurance public health functions model. This stepwise approach applies the 10 essential services of public health⁷ coupled with an adaptation from another public health program, “Planning and Implementation of a Student-led Immunization Clinic: The Thirteen-step Process”.⁸

Step 1 Conceptualize an Idea and Find an Organization with Aligned Goals

Ignite your passion for kidney disease awareness and find a professional and/or student organization with goals aligned to your passion. SNPhA's CKD initiative raises awareness every year in March during Kidney Awareness Month. Contact your local SNPhA chapter and/or other kidney organizations and find out if a collaboration can be established to host an event.

Step 2 Conduct a Needs Assessment

To ensure an effective public health intervention, a needs assessment is required. Consult the CDC's kidney disease resources and the Healthy People 2020 objectives that focus on kidney disease; and identify a location and target population with a need for kidney disease prevention education intervention. Consult your local health department to find out the prevalence of kidney disease in your area. Use the *Assessment Development and Assurance Pharmacist's Tool (ADAPT)*⁹ to ensure highest quality and greatest impact. Another helpful resource is the National Council on Patient Information and Education (NCPIE).¹⁰

Kidney Disease and Obesity

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9 March 2017



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Step 3

Set a Goal and Convene a Planning Team

Set a goal and target your plan based on your needs assessment. Reach out to the SNPhA CKD Initiative Chair of a pharmacy school within the vicinity. Plan with both the CKD Initiative Chair and the chapter president. Sell your idea to stakeholders, such as a kidney organization, community pharmacy, pharmacists, co-preceptors and/or students.

Step 4

Seek Guidance and Support

Pharmacists and/or students on APPE rotations should seek guidance from colleagues, co-preceptors, and faculty advisors of the student organizations. Preceptors should seek support from colleagues at organizational leadership levels. Also, establish a relation with regional event organizers of associations, including the National Kidney Foundation (NKF) for resources.

Step 5

Collaborate with Local Organizations

Collaborate with local health departments if possible. Visit the NKF website¹¹ and obtain contact information for the regional event organizer. Reach out and ask for assistance, including obtaining patient education materials. These individuals will most likely know the optimal location and logistics based on experiences and expertise.

Step 6

Recruit and Train Volunteers

Recruit pharmacists and/or student volunteers early to ensure their commitment. Create and send out a spreadsheet for student volunteers to sign up. Schedule a meeting with the team regularly and at three weeks before the event. Assign tasks and follow-up with responsible parties to review the event's schedule for readiness. Provide training for volunteers, as applicable to their roles and responsibilities.

Step 7

Promote the Initiative

Develop a press release and send it to local newspapers and radio stations. Seek review and input from their marketing department if available. Create flyers and display at public places, such as a libraries or common areas. Use social media sites like Facebook and Twitter to promote the event.

Step 8

Put it All Together

Confirm that all educational materials, including posters, visual-aids and logistics are ready by doing a personal check. Collect any materials from partner organizations. Visit and inspect the site. Once everything is ready, use the ADAPT tool to double check attainment of preparation goals to ensure highest quality and impact.

Step 9

Implement the Event and Manage Last-Minute Challenges

Arrange for the team to be on-site at least an hour before commencement to setup. Convene the team for a huddle session and congratulate team for their planning efforts. Anticipate and resolve last minute challenges with a positive can-do attitude. Enjoy the event.

Step 10

Follow-up and Evaluation

Invite faculty of participating institutions and/or colleagues of partner organizations to review the content of educational materials and posters created by the students. Collect emails from attendees; then, prepare and send out an online evaluation survey on the event. Complete reports for various stakeholders, such as partner organizations, student organizations and sponsors or supporters. Summarize feedback to improve future events.

In addition to the steps above, there are helpful resources and websites, such as the National Kidney Foundation (NKF)3 chronic kidney disease risk screening available at <http://nkf.worksmartsuite.com/UserContentStart.aspx?pl=11-10-1814> or risk factor card at <http://nkf.worksmartsuite.com/GetThumbnail.aspx?assetid=1761>. Additional websites include: www.kidney.org, www.aakp.org, www.kidneyfund.org, www.americanheart.org, and www.snpha.com/initiatives/chronic-kidney-disease. With systematic planning and available resources, pharmacists and/or students will be able to implement an effective and quality "Healthy Kidneys" event for patients and celebrate World Kidney Awareness Month.

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State & Federal Updates

Federal Pharmacist Provider Status Legislation Re-Introduced

HR 592, Pharmacy and Medically Underserved Areas Enhancement Act, has been reintroduced. The bill would allow Medicare Part B to utilize pharmacists to their full capability by providing services to the underserved. 19 out of 24 counties in Maryland are considered to be medically underserved. The lack of pharmacist recognition as a provider limits the ability of pharmacists to provide services that they are qualified to perform and presents a barrier to care - this bill remedies this situation. It would also reduce overall healthcare costs and increase access to healthcare services and improve healthcare quality outcomes for a very vulnerable population. If you have not already done so, reach out to your Congressional Representative via www.house.gov and express your support for the bill.

19
OUT OF
24

counties in
Maryland are
medically
underserved



FDA Bans Sale and Use of Powdered Medical Gloves

Effective January 18, 2017, the Food and Drug Administration (FDA) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling.

Consequently, FDA is banning these devices. This ban includes the use of powdered gloves by pharmacists.

CMS Recognizes Impact of Expanding a Pharmacist's Scope

In a guidance released on January 17, the Centers for Medicare & Medicaid Services (CMS) encourages state Medicaid programs to consider expanding the ability of pharmacists to prescribe, modify, or monitor drug therapy to promote patient access to medically necessary and time-sensitive drugs. CMS recognizes the need for innovative tools to address public health issues, including the expansion of a pharmacist's scope of practice by utilizing collaborative practice agreements, standing orders, or therapy protocols to treat patients.

PTCB Suspends Implementation of Accredited Education Requirement Originally Planned for 2020

The Pharmacy Technician Certification Board (PTCB) has decided to suspend the implementation of the planned 2020 accredited education requirement for pharmacy technicians who seek PTCB Certification.

PTCB originally announced in 2013 that the requirement would take effect in 2020 as part of a road map of program changes designed to keep pace with the evolution of technician roles in the pharmacy. "We have determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, Chair of the PTCB Board of Governors, and CEO of the Michigan Pharmacists Association.

HHS Rule Gives Pharmacies Flexibility with Rewards

A final rule issued by HHS allows beneficiaries in government-programs, such as Medicare and Medicaid, to participate in pharmacy customer rewards and loyalty programs. Federal laws had previously blocked government-program beneficiaries from participating in pharmacy rewards programs. This rule went into effect on January 6. ●

Member Mentions

Welcome Baby Moody!

Congratulations to House Speaker Ashley Moody, PharmD, BCACP, AE-C and husband Ross! On January 25, they welcomed baby girl Ruth Maxine. She joined the world at 9lbs 6 oz. and 22 inches long.



Past Speaker Assumes Federal Role

Past Speaker W. Chris Charles, PharmD, BCPS, AE-C has joined the Commissioned Corps of the US Public Health Service. He will be stationed at the Pine Ridge Indian Hospital providing care for the Oglala Sioux Tribe in Pine Ridge, South Dakota starting in February 2017.



Chris Charles with his daughter Emma and wife Fei in her hometown of Leshan, China

MPhA Past President joins Ranks of APhA Fellows

MPhA Past President Hoai-An Truong, PharmD, MPH, FNAP, and faculty at the University of Maryland Eastern Shore (UMES) School of Pharmacy and Health Professions, has been nominated and selected as a Fellow of the American Pharmacists Association (APhA). Fellows must have a minimum of ten years professional experience and demonstrated exemplary professional achievements and service to the profession through activities with APhA and other national, state, or local professional organizations. Hoai-An will be officially recognized during the APhA Annual Meeting and Exposition in San Francisco, CA, March 24-27, 2017.



Member to Member Ownership Transitions

John & Wayne VanWie (current MPhA Trustee) owners of Professional Pharmacy in Rosedale, MD, for more than 10 years, recently announced that they have transitioned their ownership interest to MPhA Past President Christine Lee-Wilson PharmD, clinical pharmacist and entrepreneur.

John and Wayne enjoyed serving the people of Rosedale, Whitemarsh and Essex communities providing medication services including fertility care, diabetes counseling, compounding, mental health care and immunizations. They are very confident that Christine will continue to serve the community well and expand the services with her clinical skills. Christine has expressed excitement about taking on this new challenge and opportunity.

Past Student Trustee Receives National Committee Appointment

Shannon Riggins, PharmD Candidate 2017, University of Maryland Eastern Shore School of Pharmacy was appointed to the 2017 APhA Policy Reference Committee at the 2017 APhA House of Delegates.



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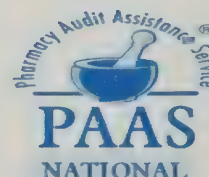


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Barriers to Optimal Health Care in the Hispanic Population: Considerations for Pharmacists

Astrid Bernal, PharmD, Graduate Pharmacist Intern, Walgreens Pharmacy

Kathleen J. Pincus, PharmD, BCPS; Assistant Professor, Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy

Learning Objectives

After reading this article, the learner will be able to:

1. Identify at least three considerations to incorporate when counseling a Hispanic patient
2. List at least three herbal products commonly used by Hispanic patients

3. Given a patient case, identify opportunities for pharmacists to improve the care of Hispanic patients

Key Words: Hispanic • Diabetes • Hypertension

Introduction

The Hispanic population is rapidly growing throughout the United States. "Hispanic" and "Latino" are terms that are often used interchangeably to describe individuals from Mexico, Cuba, Puerto Rico, Central America, and South America.¹ The National Council of La Raza, estimates that there are 50.6 million Hispanic people living in the United States.² In Maryland, Hispanics are the second largest minority group.³ The population of Hispanics in the state grew by 48% between 2000 and 2006 and is projected to continue to increase over the next several years. High rates of Hispanic patients face barriers to receiving optimal health care, including lack of health coverage and low socioeconomic status. In 2014, 27% of Hispanics living in Maryland did not have health insurance, 13% were living under the poverty level, and 56% did not own their own home.⁴ Other barriers include low education levels, cultural beliefs about health care, and difficulty communicating with health care professionals.

These social determinants impact the recognition, management, and outcomes related to common chronic medical conditions including obesity, diabetes, and hypertension.

Obesity

More than 3 in 4 Hispanics in the United States are obese, defined as a BMI > 30 or a waist circumference > 35 inches in females or 40 inches in males.⁵ Being overweight or obese increases the risk of developing other diseases including type 2 diabetes, hypertension, cancer, stroke, osteoarthritis, and nonalcoholic fatty liver disease.^{5,6} The high fat, carbohydrate, salt, and sugar content in traditional Hispanic diets may contribute to the high rates of obesity seen in the Hispanic population. Each culture is associated with signature meals. As an example, popular meals in the Puerto Rican culture, consist of pastels (meat pies), rice, beans, chicken, and other meats.⁷ While in the Mexican culture, the diet is rich in complex carbohydrates, corn, tortillas, rice, beans, meats, and spices.⁸ Many Hispanics mention

that following a diet consistent with the USDA recommendations can be challenging because it does not include traditional Hispanic foods.⁷ Hispanic cultures are typically family oriented with many celebrations incorporating traditional foods. An individual may feel like an outsider when he or she is unable to eat the same things as family and friends.⁷

Since many Hispanic immigrants also have low socioeconomic status, buying foods that are beneficial to their health may be difficult. Many immigrant communities are located in food deserts; areas where fast food and small convenient stores are readily available, while fresh produce and meats are scarce. The areas in which the majority of Hispanic immigrants live, also do not provide the safest environments for exercise. Diet and exercise are the most important factors that can help with weight loss and help reduce the risk of obesity-related diseases. While adjunctive medications to treat obesity, including phentermine and orlistat have FDA approval, they can be

expensive particularly for uninsured patients.

Diabetes

According to the U.S. Department of Health and Human Services Office of Minority Health, Hispanic adults are 1.7 times more likely to be diagnosed with diabetes than non-Hispanic whites.⁹ Biological characteristics, socioeconomic conditions, and cultural aspects contribute to the increased prevalence of type 2 diabetes.¹⁰ Increases in abdominal obesity and visceral fat have been found in the Hispanic population. This biological factor is thought to contribute to the increased risk of insulin resistance in Hispanics compared to non-Hispanic whites.¹⁰ It has also been hypothesized that Hispanics may have a genetic predisposition for B-cell dysfunction.¹⁰

Since therapies to modulate genetic risk factors are not

available, the main focus of diabetes prevention and treatment should be socioeconomic conditions and cultural aspects to decrease the disparity in diabetes-related outcomes. Studies have demonstrated a correlation between low socioeconomic status and increased risk of type 2 diabetes diagnosis and amputation.¹⁰ Low socioeconomic status can cause patients to forgo their medication due to cost or lack of insurance. Medications for diabetes, particularly insulin, can be expensive. Insulin formulations that come in prefilled auto-injectors such as Lantus Solostar and Novolog Flexpens can cost over \$300 and \$480 per box respectively.^{11,12} For a patient without insurance this can become quite burdensome. Prescribing insulin vials may reduce cost, but also increases complexity of administration, which is especially demanding for patients with poor

eyesight or conditions like arthritis that can affect manual dexterity. The additional cost of supplies including syringes must also be considered. Clinicians may turn to older insulin formulations like NPH or mixed insulins to further reduce cost (\$27 for a 10 mL vial of Novolin N), though the pharmacokinetic profiles of these formulations less closely resemble physiologic insulin production and may confer less stringent blood glucose control.¹³ These patients may also lack reliable transportation, which can limit their ability to regularly attend medical appointments.¹⁰

Hispanic cultures are rich in cultural beliefs and traditions. Hispanics have been shown to have more medication-related concerns and misconceptions about their disease state and its management when compared to non-Hispanic whites.¹⁰ Some misconceptions include: fear of

SIDEBAR CASE

Mrs. T is a 65-year-old Hispanic woman, from Mexico, who comes to your pharmacy for the first time. The patient lives at home with her daughter, son-in-law, and three grandchildren. Today she is here with her daughter, who speaks little English. She has a new prescription for Lisinopril 10 mg once daily and Metformin 500 mg twice daily. Because the patient is new to the pharmacy, you proceed to ask pertinent questions related to her health. Instead of answering the questions, the patient hands you documentation from her hospital visit. You see that

her BMI is 32 kg/m². You ask the daughter about her mother's diet and she mentions that they eat tortillas with meat, white rice, and beans about four nights a week. The mother doesn't drive, so it is difficult to get to the grocery store. Mrs. T often relies on family members for transportation to and from the grocery store and her medical appointments.

Allergies: Eggs (severe rash and stomach pain)

Medical Conditions: Diabetes, Hypertension, and obesity

Ht: 5'2" | Wt: 175 lbs | BMI: 32 kg/m² | A1C: 8%

CE QUESTIONS

1) Which of these is mentioned as a folk remedy for the treatment of Diabetes that is most commonly used in the Mexican and Guatemalan population?

- A) Manzanilla
- B) Sabila
- C) Nopal
- D) Yerba Buena

2) What is the most likely reason for uncontrolled hypertension among the Hispanic population?

- A) Lack of insurance
- B) Non-adherence
- C) Trouble getting to medical appointments due lack of transportation
- D) All of the above

3) Which of these is not a recommended resource for pharmacist when counseling Hispanic patients? (Select all the apply)

- A) Google translator
- B) Telephone service
- C) Bilingual pharmacist
- D) Family and friends

4) Which one of these foods is not listed as a popular dish in the Mexican population?

- A) Complex carbohydrates (corn tortillas)
- B) Beans
- C) Rice
- D) Pastels (meat pies)

Answers on page 17

Table 1: Common Herbal Remedies Used in the Hispanic Population

Name in English (Spanish)	Typical Uses	Common Side Effects	Drug Interactions
Aloe Vera (Sabila) ^{15,16}	Diabetes	Abdominal pain and cramps with aloe latex. Long term use can cause diarrhea, potassium depletion, etc.	Digoxin-increased risk of toxicity related to potassium depletion
Prickly Cactus Pear (Nopal) ¹⁷⁻¹⁹	Diabetes	Mild diarrhea, nausea, abdominal fullness, and headache	May increase hypoglycemic effects when given with other antidiabetic agents (e.g. glyburide)
Garlic (Ajo) ^{20,21}	Hypertension Prevention of arteriosclerosis	Malodorous breath, body odor, flatulence, weight loss, nausea, vomiting, facial flushing, insomnia	May enhance the effects of anticoagulants and antihypertensive medication
Ginger (Jengibre) ^{20,22}	Nausea Vomiting	Abdominal discomfort, heartburn, diarrhea, and a pepper like irritant effect in the mouth and throat	May enhance effects of anticoagulants

becoming medication dependent, perceptions that patients can feel when their glucose levels are high, beliefs that physicians can cure diabetes, and the impression that medication is not needed when they feel normal.¹⁰ Along with these misconceptions, other treatment beliefs and practices can affect the quality of care. Some Hispanics use folk remedies and natural medicines rather than seeking care at medical facilities [Table 1].¹⁴⁻²² Aloe vera, also known as *sabila* in Spanish, is an example of a folk remedy that Mexican and Guatemalan people believe to have hypoglycemic properties and to be helpful for the treatment of diabetes.¹⁵ In most clinical trials, *Sabila* has been found to be well-tolerated.¹⁶ Aloe latex, the part of the plant between the rind and inner gel, has been associated with abdominal pain and cramps.¹⁶ Long-term use of aloe latex can cause diarrhea, potassium depletion, albuminuria, hematuria, muscle weakness, and heart disturbance.¹⁶ Caution should also be taken with patients who are taking digoxin because of a major drug-drug interaction that increases the risk of digoxin toxicity.¹⁶ *Nopal* (prickly pear cactus) is another example of a natural remedy that the Mexican

culture believes to be helpful for preventing and controlling type 2 diabetes.¹⁷ Side effects in patients taking *Nopal* include mild diarrhea, nausea, abdominal fullness, and headache.¹⁸ Patients that are taking antidiabetic agents such as metformin and glyburide, should be cautious and monitor their blood glucose levels frequently when taking *Nopal*, as the combination can increase the risk of hypoglycemia.¹⁹ These are only a few examples of how cultural beliefs, in addition to low socioeconomic status, can play a major role in treatment for Hispanics diagnosed with diabetes.

Hypertension

Hypertension is another chronic condition that significantly impacts the Hispanic population. It is one of the leading causes of heart disease and stroke in the United States affecting one in every three adults.²³ Approximately \$46 billion dollars are spent in this country on health care services, missed days of work, and medications used to treat high blood pressure.²³ According to the National Health and Nutrition survey, when compared to non-Hispanic whites and non-Hispanic blacks, Hispanics were the population associated with the

least controlled hypertension.²⁴ A study done by Tong and colleagues reinforces this finding. This study found that Hispanic patients had the highest percentage of uncontrolled hypertension due to non-adherence, when compared to non-Hispanic blacks and whites.²⁵ Younger adults and those with low socioeconomic status were also associated with having low adherence rates. The most commonly reported reason for non-adherence among the Hispanic population, was not feeling that they needed to control their blood pressure.²⁵ Factors relating to non-adherence in this population included, language barriers, cultural beliefs, lack of health insurance, lower income, and low health literacy.²⁵ Interventions including community health workers or promoters de salud, were mentioned as possible options to improve disease state education for the Hispanic population.²⁵ Increasing screening and awareness of the importance of controlling hypertension has the potential to have a significant impact on the progression to other cardiovascular diseases such as coronary artery disease, stroke, and heart failure.²⁶ The barriers of low socioeconomic status, limited access to healthy foods

and safe places to exercise, low health literacy, language barriers, are repeating themes that have the potential to impact many chronic disease states.

Pharmacist Training

Not only is it important for healthcare professionals to be educated on these barriers, but it is also important to learn about each patient's culture, diet, and beliefs related to medications and healthcare. Cultural competency is defined as having a "set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in cross-cultural situations."²⁷ Having an understanding of cultural competency is essential for providing optimal care in the growing Hispanic population. Pharmacists play an integral part to a patient's overall care and it is important to provide education early in training to optimize the delivery of pharmaceutical care to these populations. Cultural competency is a topic most often taught in pharmacy school through didactic or case based lessons, but not as consistently encountered through experiential education.²⁷ Adding an advanced pharmacy practice experience (APPE) that incorporates interaction with Hispanics or other minorities would help translate what is taught in class into real life practice.²⁷ In a study done at Drake University College of Pharmacy and Health Sciences, 43 students completed a Community Access Pharmacy APPE, which allowed them to engage with a culturally diverse population.²⁷ Students interacted with patients in the Hispanic community, homeless shelters, and at HIV Clinics. When interacting with the Hispanic patients, students had the opportunity to participate in various activities. Students practiced with Spanish interpreters and learned how to use a language

line service when interpreters were not present. Students were also given the opportunity to visit a Hispanic grocery store to become familiar with the foods sold there.²⁷ In addition to visiting the grocery store, they provided a nutritional plan for a Hispanic woman with diabetes. They spent some time with her at the grocery store, educated her on how to interpret food labels, and taught her how to measure serving sizes. This was essential to her diabetes education and treatment plan. Incorporating experiences such as this, helps increase student pharmacists' awareness of the challenges Hispanics face on a daily basis and allows them to become more understanding and empathetic healthcare professionals. Another topic that is discussed in the literature is the incorporation of a Spanish course in pharmacy school. In an article written by Dilworth and colleagues, it is mentioned that pharmacists feel that Spanish courses should be incorporated into pharmacy school, required as a prerequisite to pharmacy school, or be made part of a continuing education for pharmacists.²⁸ With the Hispanic population expected to increase rapidly over the next several years, it is important to educate pharmacists early in their training so that they can be better prepared.

Pharmacists' Role

Pharmacists practice in a variety of settings that require interaction with patients from different cultures and backgrounds. Whether in a hospital, outpatient clinic, or community pharmacy, the interaction between the patient and pharmacist is a vital part in providing optimal care [Table 2]. Pharmacists not only provide medication education and counseling, but they can also help make non-pharmacologic recommendations on topics such as diet and exercise. Establishing

a collaborative pharmacist-patient relationship through good communication skills can help improve medication adherence and reduce adverse drug events, which research has noted to be prevalent in patients who have limited English proficiency.²⁸ Reducing adverse events and improving medication adherence can help reduce healthcare costs and improve health care outcomes. Pharmacist can also play a role in promotion of preventative health screenings in the Hispanic population, by stressing the importance of immunizations and cancer screenings. Hispanics and Blacks are both mentioned as the populations less likely to receive preventative health screenings because of barriers to receiving health care, in comparison to Whites.²⁹

Establishing an environment in which the Hispanic patient feels comfortable discussing his or her views, beliefs, and disease state understanding will help the patient feel connected to the healthcare team and encourage their active participation in their own treatment including attending regular follow-up appointments and adherence to medications. Communication can become difficult due to language barriers, but pharmacists should familiarize themselves with available interpretation resources. Some of these resources include computer programs that help translate pharmacy labels and educational brochures into Spanish, and interpreters. Interpreters can take on many forms, which may include internet services, telephone services, scheduled live interpreters, bilingual pharmacists and/or staff, and a patient's family member or friend.²⁸ Caution should be taken when using family members or friends as interpreters because they may not be able to accurately interpret the information given by the pharmacist.²⁸ Family members may not know medical

Table 2: Counseling Tips for Pharmacists Interacting with a Hispanic Patient**Communication**

- Familiarize yourself with available interpretation services at your practice site
- Evaluate patient's level of education and acculturation (e.g., years of education, fluency in English)
- Avoid using family members as medical interpreters whenever possible
- Maintain eye-contact with the patient when using an interpreter
- Use short sentences with frequent breaks
- Request written information from hospitalizations and/or outpatient appointments to help clarify diagnoses, history, and instructions
- Provide written documentation of your conversation with the patient that they can show to other healthcare providers

Dietary Counseling

- Ask the patient to characterize their typical diet
- Become familiar with foods typical of the patient population, visit local Hispanic grocery stores
- Individualize counseling on dietary modifications to include traditional foods
- Focus on portion control
- Assist patients in identifying stores in their area where they can purchase fresh foods

Exercise

- Assist patients in developing specific exercise plans
- Help patients identifying safe and affordable locations to exercise

Preventative Medicine and Health Care Access

- Ensure that patients are screened for common medical conditions including: obesity, diabetes, and hypertension
- Promote preventative medicine including immunizations and cancer screenings
- Identify community based resources in your area including community health workers, low cost health centers, charity services, English Speakers of Other Languages (ESOL) classes

Medication Access and Understanding

- Assess patient's prescription coverage before making pharmacotherapeutic recommendations
- Reinforce goals of therapy and the role of medications for long term control of chronic conditions
- Assess for adverse effects of medications
- Assess patient's medication and medical beliefs
- Ask the patient about the use of herbal products and folk remedies
- Identify resources to help defer prescription costs: eligibility for prescription drug coverage, manufacturer coupons, and pharmacy discount cards

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terminology either in English or in Spanish and may alter messages due to compassion for a loved one. Family members may also be embarrassed to ask certain sensitive questions particularly to an elder. When using interpreter services, it is important for the pharmacist to maintain eye contact with the patient and avoid long statements that may overwhelm the patient. Pharmacists can also request that the patient provide written documentation from hospitalizations or doctors' visits. This can help the pharmacist

piece the puzzle together when learning about the patient as a whole and what is beneficial to their care. Since many of these patients also cannot afford their medications, identifying resources, finding coupons (if available), or enrolling patients in pharmacy discount programs can help defer medication costs and reduce the prescription payment burden on the patient. Lastly, pharmacists can become familiar with foods typical to the patient population they serve and become aware of community programs that can help

the Hispanic population in the area. Some examples include English for Speakers of Other Languages (ESOL) classes, health promoters, and charity based programs. As a healthcare community, we have seen positive progress with aiding the Hispanic community, but there is still room for improvement. Future research should be geared towards implementing programs that can help train pharmacists to optimize interactions with minority populations.

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This program is Knowledge Based — acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

This issue's quiz on **Barriers to Optimal Healthcare in the Hispanic Population: Considerations for Pharmacists** can be found online at www.PharmCon.com.

- (1) Click on "Obtain Your Statement of CE Credits for the first time.

- (2) Scroll down to Homestudy/OnDemand CE Credits and select the Quiz you want to take.

- (3) Log in using your username (your email address) and Password MPHA123 (case sensitive). Please change your password after logging in to protect your privacy.

- (4) Click the Test link to take the quiz.

Note: If this is not the first time you are signing in, just scroll down to Homestudy/OnDemand CE Credits and select the quiz you want to take.

CE Questions Answers from page 14

1) B. Sabila also known as Aloe, is used by both the Mexican and Guatemalan population. Manzanilla (chamomile) is used for colic or upset stomach. Yerba Buena (spearmint) is typically used to relieve upset stomach and headache.

2) D. All are contributing factors for uncontrolled hypertension in the Hispanic population.

3) A and D. It is important to use a reputable source when providing translation. Family and friends aren't the best resource because they may alter language out of compassion for their loved one.

4) D. Pastels (meat pies) are more common among those of Puerto Rican decent.

PHARMACISTS MONTH ACTIVITIES

MPhA-Rite Aid Flu Shot Clinic

In collaboration with our Corporate Sponsor Rite Aid, MPhA hosted a Flu Shot Clinic. Patients included employees from the business park where MPhA headquarters is located. While waiting for their shots, patients were treated to a tour of the pharmacy exhibits and received ScriptYourFuture resources. It was a fun day to meet our neighbors, provide flu shots, and educate them about the role of pharmacists in Maryland.



MPhA Provides Educational Support to Prevent Medication Errors

MPhA held its October CE focused on medication safety in cooperation with the Food and Drug Administration (FDA). Thank you to Kimberly DeFronzo, FDA, Division of Drug Information, for facilitating the collaboration and to presenter Mishale Mistry, PharmD, MPH for presenting, "Ongoing Role of FDA in Medication Error Prevention." The meeting room was packed and feedback from participants was overwhelmingly positive. Participants appreciated the greater understanding of the role of FDA plays in medication safety and the impact pharmacists have in the organization.

Maryland Preceptors Gather at MPhA Headquarters

In collaboration with the University of Maryland Eastern Shore, Notre Dame of Maryland University and the University of Maryland Baltimore schools of pharmacy, MPhA hosted a

preceptor workshop entitled, "Adopting the Pharmacists' Patient Care Process (PCPP) to Optimize Patient Care Outcomes." The goal of the workshop was to bring together preceptors who serve pharmacy schools in Maryland to promote consistency in patient care service delivery across the profession. The Pharmacists' Patient Care Process is intended to be used for a wide array of patient care services as authorized under pharmacists' scope of practice and delivered in collaboration with other members of the health care team. Workshop developers and presenters are pictured below.



Left to right: Drs. Mark Brueckel, Tosin David, Nicole Culhane, Min Kwon, Sherry Moore and Mark Freebery

Door Prize winner at Preceptor Workshop

First Quarter 2017: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1992

- The American Association of Colleges of Pharmacy (AACCP) passed a resolution supporting a single entry level professional degree.
- Psychiatric pharmacy recognized as a specialty by the Board of Pharmacy Specialties (BPS).

1967

- Donald Brodie articulated the concept of drug use control which would become the central precept of clinical pharmacy and later pharmaceutical care.

1942

- American Foundation for Pharmaceutical Education incorporated in 1942 to provide financial support to colleges of pharmacy in need during World War II and later finance the Elliott Report.

1892

- Original passage of Utah Pharmacy Practice Act
- University of Minnesota College of Pharmacy founded by Dean Wulling

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Maryland Pharmacists Association is a member of AIHP. The Past Presidents' Council's History Committee are using their resources to aid in documenting the history of MPhA.

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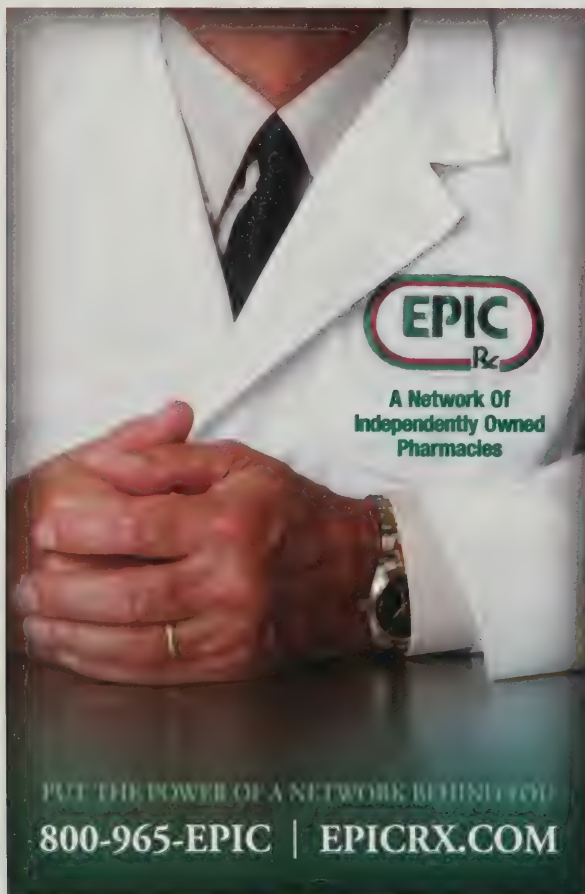
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Version III: Important Information Regarding Maryland Prescription Drug Monitoring Program

The Maryland Prescription Drug Monitoring Program (PDMP) was created to support providers and their patients in the safe and effective use of prescription drugs. The PDMP is part of Maryland's response to the epidemic of opioid addiction and overdose deaths.

Maryland PDMP Facts

- Authorized by law in 2011
- Maryland Department of Health and Mental Hygiene (DHMH) program
- Contains data on Rx controlled dangerous substances (CDS) dispensed to patients in Maryland
- Providers get free, online access through Chesapeake Regional Information System for our Patients (CRISP) at: www.crisphealth.org

What is CRISP?

- State-designated health information exchange (HIE) serving Maryland and the District of Columbia.
- Electronic system connecting all 46 acute care hospitals in Maryland
- Web-based portal gives providers secure access to patient PDMP, hospital and other clinical data

Legal Changes Affecting Providers

On April 26, 2016, Governor Hogan signed into law HB 437 which includes the following legal changes:

1. Mandatory PDMP Registration for CDS Prescribers & Pharmacists

Pharmacists: Licensed pharmacists in Maryland must be registered with the PDMP by **July 1, 2017**.

Prescribers: Practitioners authorized to prescribe CDS in Maryland must be registered with the PDMP by **July 1, 2017**. This

applies to physicians, physician assistants, nurse practitioners, nurse midwives, dentists, podiatrists and veterinarians. This mandate does not apply to the following categories of nurses: RNs, CNAs, and LPNs.

Version 3.0, September 30, 2016

Please note: a second provision in the law will, in the future, require PDMP registration prior to obtaining a new or renewal CDS prescribing permit from the Office of Controlled Substances Administration (formerly Division of Drug Control) after a positive determination is made by the DHMH Secretary, expected to occur July 1, 2017; that provision of the law is NOT in effect at this time.

2. Mandatory PDMP Use by CDS Prescribers & Pharmacists

Beginning July 1, 2018:

Prescribers: Must, with some exceptions, query and review their patient's PDMP data prior to initially prescribing an opioid or benzodiazepine AND at least every 90 days thereafter as long as the course of treatment continues to include prescribing an opioid or benzodiazepine. Prescribers must also document PDMP data query and review in the patient's medical record.

Pharmacists: Must query and review patient PDMP data prior to dispensing ANY CDS drug if they have a reasonable belief that a patient is seeking the drug for any purpose other than the treatment of an existing medical condition.

Information regarding Mandatory Use is available on the DHMH PDMP website. DHMH will provide additional information and reminders closer to but before the implementation date.



REGISTER NOW with the PDMP through CRISP at www.crisphealth.org.

Look for the PDMP 'Register' button on the homepage or on the PDMP Services page.

For registration help, call CRISP Support at: 1-877-952-7477.

3. CDS Prescribers & Pharmacists May Delegate PDMP Data Access

Prescribers and pharmacists may delegate healthcare staff to obtain CRISP user accounts and query PDMP data on their behalf. Delegates may include both licensed practitioners without prescriptive authority and non-licensed clinical staff that are employed by, or under contract with, the same professional practice or facility where the prescriber or pharmacist practices.

To Learn More

Visit the DHMH PDMP website for updated information, important compliance dates and Frequently Asked Questions: <http://bha.dhmh.maryland.gov/PDMP>.

For more information about the opioid addiction and overdose epidemic in Maryland and what healthcare providers can do to help, visit http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/.

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Executive Director's Message

Are you ready? Legislative Session is on! Our elected leaders are in place. We are ready to work with our allies and educate others about issues that are important to pharmacy practice and the patients you serve.

As pharmacists, pharmacy technicians and student pharmacists you understand the professional world you work in, and the day-to-day challenges and opportunities afforded the profession. Our lobbyists from G.S. Proctor & Associates facilitate our entry to key committees and legislative leaders in Annapolis and Washington, DC. We collaborate with elected leaders to highlight the impact you have on patients' lives.

The Mid-Year Meeting was a great opportunity to learn more about the policy and legislative changes taking place at the national and state level, and how we work collaboratively with our pharmacy colleagues in Maryland.

With the ascension of Delegates who have shown support for the pharmacy community to greater leadership positions in Annapolis, we are taking advantage of opportunities. We participated in a pharmaceutical services briefing with members of the Health and Governmental Operations Committee in early February. The briefing was a fantastic opportunity to share our story with the full committee.

National legislation, the Pharmacy and Medically Underserved Areas Enhancement Act (S 109/HR 592), has been reintroduced in Congress. MPhA is in support of this legislation that will allow pharmacists to be designated as healthcare providers under Medicare Part B. This legislation will enable pharmacists to fill healthcare voids, broaden services and be compensated for their work. As you may know, 19 out of 24 counties in Maryland are considered to be medically underserved. We are working to build Maryland delegation support for this important effort.

Remember MPhA is your advocate.

- We are promoting pharmacy
- We are defending pharmacy practice
- We are arguing for pharmacists to work at the height of their education and to be paid for it

Your continued support enables MPhA to maintain these activities. What can you do to continue the momentum?

- 1) Share your concerns/questions with MPhA. We work with elected leaders and the Board of Pharmacy to get the answers and changes you need.
- 2) Get to know your elected leaders. Members of the General Assembly are accessible and open to gaining knowledge from their constituents. Find out who represents you in



Annapolis and in Washington, DC at <http://mdelect.net/>.

- 3) Read the *Monday Message* and other communications from MPhA and take requested actions.

If you haven't done so already, be sure to renew your membership. We need you in the fight to protect and advance pharmacy practice in the state. ●

Respectfully,

Aliyah N. Horton, CAE
Executive Director

WHAT'S NEW?

Partnering for Pharmacist and Patient Education Resources

MPhA has partnered with Health Quality Indicators to participate in a national initiative to improve population health. Our involvement provides access to resources for pharmacists to improve cardiac health and diabetic care with resources in English and Spanish. The partnership provides web resources and access to free webinars for MPhA members. In addition, the program has a "blue bag" initiative to support medication adherence. Visit www.marylandpharmacist.org for more information.

New Look to MPhA Career Center

MPhA Career Center has new enhancements to provide both employers and job seekers with a better user experience. New Career Resources content has been added as well as a "Jobs You May Like" option, which support a more personalized job search experience. The Career Center can be accessed via the MPhA Website.

Emergency Preparedness Task Force

An Emergency Preparedness Task Force was appointed to identify and collect resources that will be useful for pharmacies and pharmacists to be prepared in times of natural or man-made disasters. The final products will be available via the MPhA website. If you are interested in working on this project contact Task Force Chair, Cherokee Layson-Wolf at cwolf@rx.umaryland.edu.

Tech-Check-Tech Task Force

The Board of Trustees is looking at opportunities to identify new practice models that will enhance the ability of pharmacists to practice at the height of their degrees and optimize patient outcomes. A recent effort is the appointment of a Tech-Check-Tech Task Force. The Task Force is bringing together stakeholders from various practice settings to collect member thoughts and ideas related to the opportunities and barriers to implementing a Tech-Check-Tech Pilot program in the community setting. MPhA is working in concert with the Maryland Society of Health System Pharmacists.



Visit MPhA Website for more details

March 25

*Maryland Pharmacy Night Reception —
APhA Convention, San Francisco, CA*

April 1

*Spring Ahead Your Pharmacy Career —
MPhA Headquarters*

April 23

*Strategies and Tools for Improving
Medication Adherence and Safety —
MPhA Headquarters*

April 29

MPhA Class of 2017 Graduation Social

May 11

*MPhA Public Board of Trustees Meeting
— MPhA Headquarters*

June 23–26

*135th Annual Convention — The Lodge
at Wisp, McHenry, MD*

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HIGHLIGHTS INCLUDE:

- CE on the most current trends in the pharmacy profession
- Opportunities to network, connect, and re-connect with your peers
- Chances to gain new perspectives from our dynamic speakers
- Recognition of professional accomplishments
- Social activities all ages may enjoy

We hope you will come join us to broaden your knowledge in the pharmacy profession.

MPhA News

135th Annual Convention:
Taking Pharmacy to
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Advocacy

Highlights of 2017 Session
of the Maryland General
Assembly

Editorial Article

Rx and the Law: Indemnification

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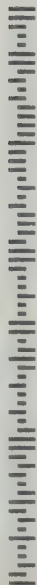
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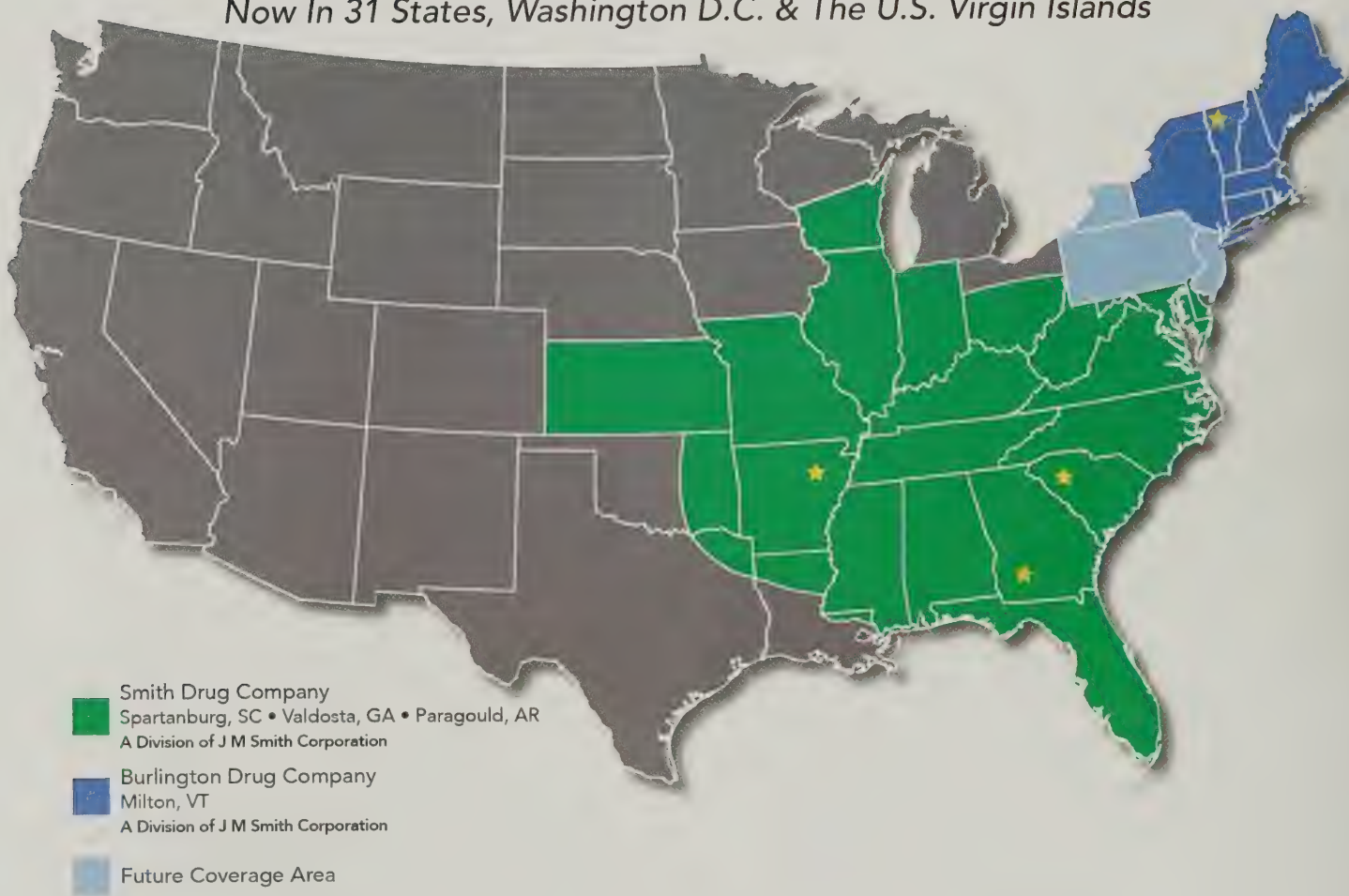
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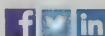


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Highlights of the 2017 Session of the Maryland General Assembly

The 2017 legislative session in Maryland was extremely active, with nearly 50 bills reviewed by the MPhA Advocacy Committee. This session demonstrated that Delegates are gaining understanding of the role pharmacists can play as integral members of the healthcare team, and for good or naught are incorporating pharmacists into legislation to address critical healthcare needs in Maryland.



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Happy Spring!

We are off to a running start in 2017 and MPhA has been busy at work for you. We kicked off the year with our Annual Mid-Year Meeting in February and had a wonderful opportunity to network while enjoying clinical updates, discussing career development, and learning about issues impacting our profession.

Our Professional Development Committee, in conjunction with our fantastic APhA student chapters from University of Maryland Baltimore, University of Maryland Eastern Shore, and Notre Dame of Maryland University, held "Spring Ahead in Your Pharmacy

Career," a day of interactive learning which focused on the development of key leadership skills and highlighted numerous opportunities in pharmacy and research.

On the legislative front, we have seen the most active legislative season to date with over 45 bills related to pharmacy. MPhA has been engaged in statewide efforts to track and respond to each these bills to ensure that pharmacists voices are heard as issues related to our profession are discussed. Our Legislative Committee, lobbyists, Aliyah, and many of you have dedicated hours to actively engaging our delegates, drafting, and providing testimony at the bill hearings. We have seen some success in several key areas that will greatly impact Maryland pharmacy including:

- The Pharmacy Intern Law: First year pharmacy students are now able to register as interns at the beginning of their school year, rather than waiting until the completion of their first year. This will allow them to put what they are learning into practice and benefit from an additional year of honing their pharmacist skills under the tutelage of seasoned pharmacists.
- The Pharmacists Prescribing and Dispensing Contraceptives Bill: PASSED!! This is the first time pharmacist "prescribing" is officially in the law. Maryland is the 4th state to enact legislation and we are thrilled to be on the forefront of increasing access to care for patients.
- Drug Pricing and Transparency: There has been a lot of controversy surrounding this topic over the past year. The legislature has begun an in-depth look at the stakeholders involved in the process of getting medications from research development to the patients. MPhA is an active participant in these discussions and will continue to engage key leaders to ensure that pharmacists on the front line have the ability and opportunity to provide the best care for patients.

We are gearing up for end of school year events – celebrating the year's accomplishments with our students and welcoming the new pharmacy graduates into the "real pharmacy world" as new practitioners!

We look forward to our Annual Convention in Deep Creek at the end of June. Keep an eye on the website and the Monday Message for updates on some of the fun events that we will be having at the convention, as well as upcoming events at our headquarters.

I look forward to seeing you in Deep Creek! ●

Kristen M. Fink

Kristen Fink, PharmD, BCPS, CDE
President

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Rx and the Law | INDEMNIFICATION

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

John from Anytown Pharmacy is negotiating to become the supplier of prescriptions and other pharmacy services to the county jail. As a possible vendor to the county, John is presented with a contract covering this relationship. One of the paragraphs is entitled, "Indemnification". John reads through the paragraph, but he doesn't really understand it. In his eagerness to win the contract, John signs it and returns it to the county. What is Indemnification and was it wise for John to agree to it before he understood it?

Indemnification is "... the obligation [or duty] resting on one person to make good any loss or damage another has incurred or may incur by acting at his request or for his benefit."¹ It is also known as a Hold Harmless agreement. What it boils down to is if the county gets sued for something Anytown Pharmacy has done wrong; Anytown Pharmacy will defend the county. This can account for significantly higher defense costs, such as attorney fees, to be incurred by Anytown Pharmacy. The pharmacy may also be paying the county's portion of any judgment in the case.

Indemnity agreements can be one-sided or mutual. A mutual indemnity agreement provides for each party to protect the other. However, a one-sided agreement requires only one party has to protect the other. This is a very important distinction and could result in significant

costs for the indemnifying party. Anytown Pharmacy should review the agreement to ascertain what it provides. Many vendor agreements as presented do not provide for mutual indemnity.

Another important part of the review is to know what acts qualify for indemnification. Most commonly, indemnification is provided for breach of contract. Other actions that can be covered by indemnification include negligent acts, grossly negligent acts, wanton & reckless acts, intentional acts, and criminal acts. These are listed in an ascending order of seriousness under the law. Part of the pharmacy's negotiations should be the types of acts that are covered by the indemnification agreement. This is important because many parties entering into such agreements assume that their insurance will take care of this indemnification. However, this is not always true as most insurance policies will likely not provide any coverage for breach of contract, intentional acts or criminal acts. The insurance policy is a contract between the pharmacy and the insurance company and it is unaffected by any contract between Anytown Pharmacy and the county. Any promises to indemnify made by the pharmacy that are not covered by insurance will have to be paid by the pharmacy.

The acts are not the only key element in the Indemnification agreement. The types of indemnity

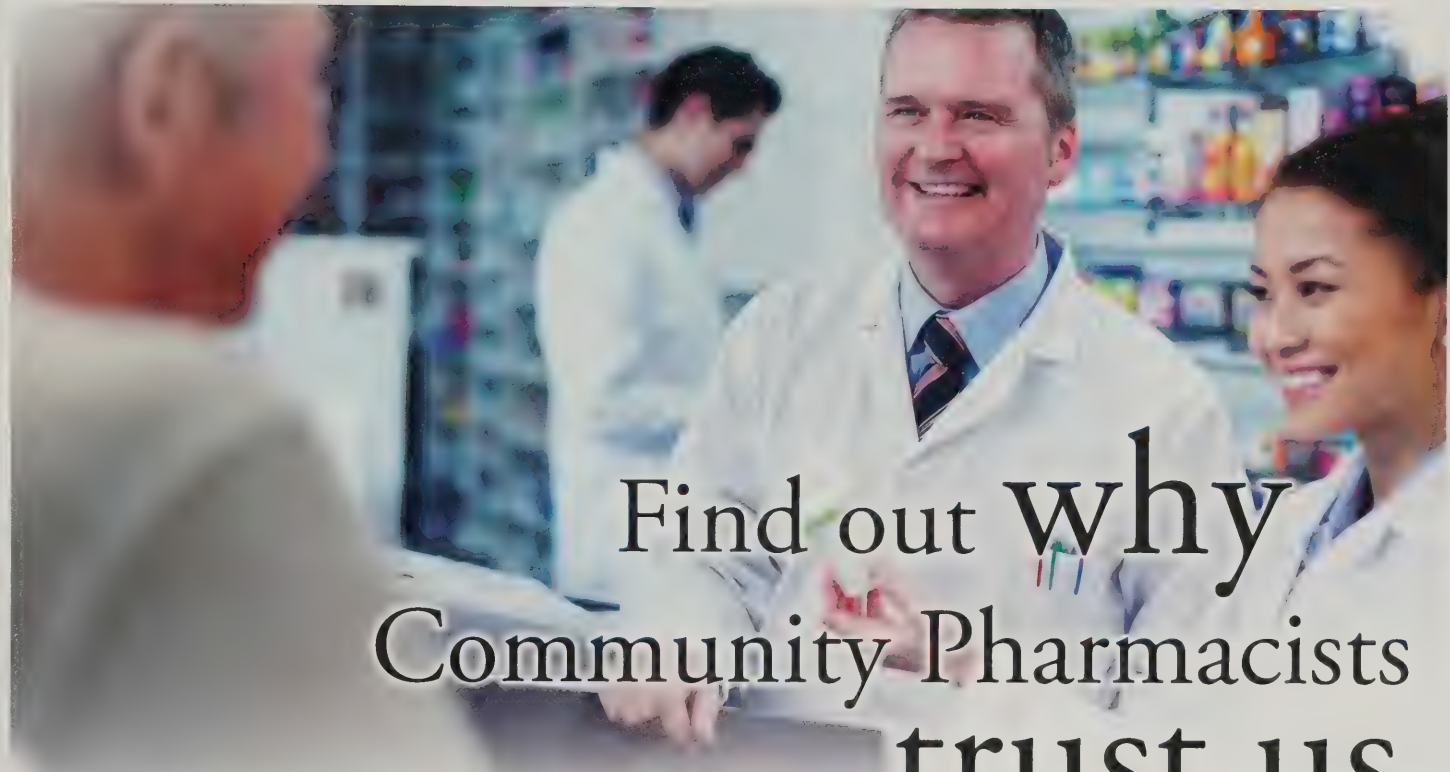
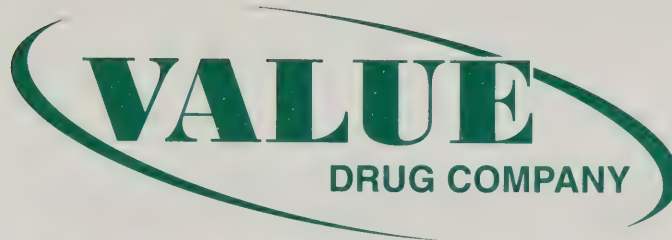
payments provided can also be listed. Examples of these payments include: any and all losses, claims, expenses, fines, penalties, damages, judgments or liabilities. Again, there may be payments promised within the Indemnification agreement that are not covered by insurance, such as fines and penalties.

The Indemnification agreement may also provide the procedure that the party requesting indemnification has to follow in order to qualify contractually. This usually involves promptly notifying the other party and providing relevant documents to them. The party asking for indemnification has to cooperate in the defense of the claim with the other party and may have input into the choice of the lawyer who will defend the case. The choice of lawyer can be critical to the success of your case, but this language has the potential to create a disagreement when it comes time to make the choice.

Depending on the language contained in the county's contract, John may have made an expensive promise because he didn't fully understand what he was agreeing to in promising to indemnify the county. Obviously, if nothing goes wrong, the issue is moot. But hope is not the best risk management strategy. Careful review of the content of the entire contract, including indemnification requirements, before signing it is a more reliable strategy. ●

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company..

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.



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Member Mentions & News You Can Use

MPhA at APhA

Maryland Pharmacy Night

Fun was had by all! A great event sponsored by MPhA and the three schools of pharmacy. It was a wonderful opportunity to connect with friends, colleagues and classmates. The reception was also a time to highlight the MPhA members making an impact at APhA!



(L-R) Ashley Moody, Larry Hogue, Matt Shimoda, Anne Lin, Brian Hose and Hoai-An Truong

Nominees for Office

Two MPhA Past Presidents are on the ballot for national office. Magalay Rodriguez De Bittner for APhA Trustee and Hoai-An Truong for APPM Member-at-Large.

Tolani Adebajo (UMES) and Meryam Gharbi (UMB) both ran for APhA-ASP Member-at-Large. Congratulations to Meryam for winning the seat and to Tolani for being the first UMES student to run for APhA-ASP national office.

Additional Recognitions

Hoai-An Truong — APhA was recognized as an APPM Fellow. Mayrim Millan — Barea (NDMU) received the APhA — ASP Student Leadership Award. David Sproul was the first UMES student to place in the top 10 in the national patient counseling competition.

Thank you to the Members of MPhA who served as delegates in the American Pharmacists Association House of Delegates in San Francisco March 24–27. The policies adopted during the session are now official APhA policy and can be found at <http://bit.ly/2pmAZUS>.

Holstein and Wherley Recognized

Certificates of Recognitions were presented to Shelby Holstein and Andrew Wherley during the 2017 Mid-Year Meeting for their role in advancing the Pharmacy Technician Network during the past year. The Technician Network continues to see growth in numbers and in participation at MPhA Meetings.



Spring Ahead in your Pharmacy Career

Students from the three schools of pharmacy in Maryland, University of Maryland School, Notre Dame of Maryland University and the

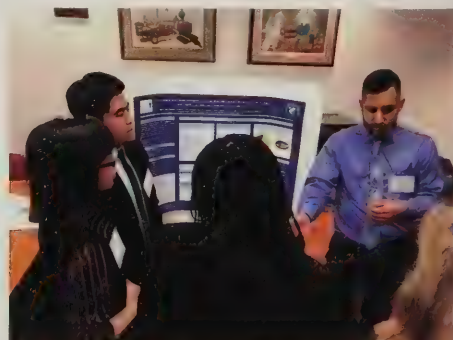
University of Maryland Eastern Shore and the Professional Development Committee hosted collaborative event to get students ready for their professional careers. Students learned about conflict management and email etiquette and were able to network with pharmacists in a wide variety of practice settings across Maryland. Students also had the opportunity to present research projects to their peers and to pharmacists. Thank you to CVS Pharmacies for supporting the event.



One of the many interactive sessions



Student and new practitioner planners of the event



Student poster presentation

2017 Mid-Year Meeting — Columbia, MD

By Bonnie Li-McDonald

The great weather on February 12 fostered a festive atmosphere where MPhA members and colleagues gathered to learn about the latest and greatest in pharmacy. The meeting covered clinical and policy topics as well as practice innovations.

Trash the Ash: A Best-Practice Approach for Smoking Cessation

Dr. Yen Dang reviewed the latest best-practice approaches for smoking cessation. Combination nicotine replacement therapy consisting of rescue (e.g. nicotine gum) and maintenance (e.g. bupropion, nicotine patch, varenicline) drugs is the most effective treatment for smoking cessation. She also presented the latest studies on varenicline related to mental health side effects and cardiovascular risks.

Pharmacists Protecting an Aging Population

Dr. Michelle Fritsch engaged attendees on a discussion around changes due to the aging process. She briefly reviewed the pharmacokinetic and pharmacodynamics consequences of medications in the aging body. She also provided useful resources for identifying fall risk using the CDC Stopping Elderly Accidents, Deaths & Injuries (STEADI) tool and how to address these risks with the ASCP/ National Council on Aging (NCOA) Tool. She also introduced the Fall Risk Inducing Drugs (FRID) list that identifies drugs that may increase fall risk in aging patients.

Self Care: The Comprehensive Approach

Drs. Loren Kirk and Monet Stanford discussed the history of over-the-counter (OTC) drugs and how they contribute to improving patient care. They emphasized how pharmacists are in the best position to explain indications, benefits, and risks of OTCs to allow patients to make more empowered decisions. They also engaged attendees in a discussion on which drugs could potentially become available OTC.

Mobile Health and Remote Monitoring in Pharmacy

Dr. Joey Mattingly reviewed the latest in mobile health apps for chronic diseases and the ethical questions surrounding this new development in health care. Mobile health apps (Buddy, Health, MyFitnessPal) are useful tools that can help monitor health conditions such as diabetes, blood pressure, and weight management. The challenges and barriers to mobile health and monitoring in pharmacy are privacy concerns, security, and literacy of the patient population. More research and better processes are needed to improve this fast-growing field.

HIV 101- Basics of HIV Patient Care

Dr. Richard DeBenedetto reviewed the most up-to-date HIV combination therapies and quizzed attendees on correct vs. incorrect regimens, drug-drug interactions, and ways to help patients improve adherence to their medications.

State and National Legislative Update

GS Proctor & Associates Lobbyists G. Steve Proctor and Sherrie Sims spoke about the increased legislative activities for the year, especially bills impacting pharmacy. Alicia Kerry Mica from APhA provided a national update on provider status. Dr. Chai Wang helped educate pharmacists and students on how to advocate for patients and the profession of pharmacy on a regular basis and in particular, as part of the Maryland Pharmacy Coalition's Advocacy Day. See the Maryland Legislative Session Recap on page TK for a wrap-up of the outcomes.

Advancing Your Pharmacy Technician Career

Zachary Green and Dr. Tara Feller shared how the recent changes within the pharmacy profession impacts pharmacy technicians. They identified the evolving roles of pharmacy technicians in assuming more technical activities to free time for pharmacists to be engaged in more clinical and patient care interactions. They provided updates on regulatory changes in various states and encouraged technicians to become involved in association activities.

Medication Safety Error Prevention – The Role of the Pharmacy Technician

Richard D'Ambrisi provided a step-by-step process for how pharmacy technicians should be able to identify and describe medication errors, determine the cause of such errors, and work towards reducing them. The session empowered technicians to recognize the significant role they play in reducing errors in the pharmacy and directed them towards resources to assist them in this expanded role.

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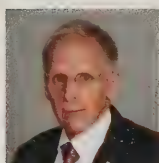
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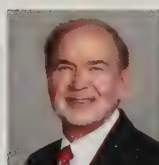
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The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@nasp.us. The Bowl of Hygeia is on display in the APhA Awards Gallery located in Washington, DC.

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Member Mentions *continued from page 8*

Script Your Future Medication Adherence and Safety Program

MPhA's Script Your Future Program hosts an annual event to bring together healthcare and business stakeholders to discuss medication adherence and safety. The 2017 Program was chaired by Yen Dang, Pharm D, University of Maryland Eastern Shore School of Pharmacy and sponsored by the Maryland P3 Program. Prior to the CE program, Pfizer provided a presentation on Pneumococcal Vaccination Delivery and Adherence Program. Speakers include James L. Bresette, PharmD, USPHS, CAPT (Ret.), University of Maryland Eastern Shore School of Pharmacy; Hoai-An Truong, PharmD, MPH, FNAP, University of Maryland

Eastern Shore School of Pharmacy; John Miller, BS, MidAtlantic Business Group and Cynthia Warriner BS, RPh, CDE, Health Quality Innovators.

Seeking Volunteers for MPhA's Maryland Pharmacy Law Book Update

MPhA is embarking on a reboot of our Maryland Pharmacy Law Book. The effort is being led by Matt Balish and Julie Mathias. The intent is to make the book more user-friendly for students practicing for law exam review and to address FAQs by practicing pharmacists. If you are interested in working on this project, please contact Julie at jul2486@gmail.com or Matt at mdbalish@gmail.com.

Specific volunteer roles that need to be filled:

1. 2016 Graduate who could co-write the section on "Helpful Suggestions to Study for MPJE."
2. Institutional Pharmacy Chapter – pharmacist who works in institutional pharmacy
3. Long Term Care Pharmacy Chapter – pharmacist who works in long term care pharmacy
4. Anyone else who would like to get involved

The current law book and update is available for purchase at www.marylandpharmacist.org under RESOURCES. ●

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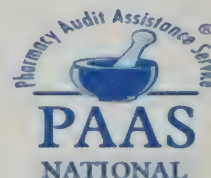


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Highlights of 2017 Session of the Maryland General Assembly

The 2017 legislative session in Maryland was extremely active, with nearly 50 bills reviewed by the MPhA Advocacy Committee. This session demonstrated that Delegates are gaining understanding of the role pharmacists can play as integral members of the healthcare team, and for good or naught are incorporating pharmacists into legislation to address critical healthcare needs in Maryland.

We kicked off the season with the Maryland Pharmacy Coalition's (MPC) Legislative Day on February 12. The group received greetings

from House Speaker Pro Tem Adrienne A. Jones and Delegate Shelley Hettleman. In addition, participants were recognized before

the General Assembly by Senate President Mike Miller and House Speaker Michael E. Busch. More than 300 pharmacists and student



Delegate Shelley Hettleman and Speaker Pro Tem Adrienne A. Jones with Legislative Day participants.

pharmacists blanketed the General Assembly with the consensus positions statements of MPC. While MPhA continues to build its brand in Annapolis, our participation in MPC enables pharmacy to have an all-encompassing voice and cohesive message on pharmacy issues. For more information about MPC and Legislative Day visit www.marylandpharmacist.org and click on the Advocacy tab.

SIGNIFICANT

Pharmacist Prescriptive Authority

Expands the scope of practice for a licensed pharmacist to include prescribing contraceptive medications and self-administered contraceptive devices approved by the US Food and Drug Administration. Maryland is the fourth state in the country to approve this type of prescriptive authority. MPhA with other stakeholders will provide consultation to the Board of Pharmacy to develop the regulations. Pharmacists must provide written information on the importance of following up with a practitioner and provide the patient with a copy of the assessment information.

Regulations will be required regarding the pharmacist's education. The requirements will be waived for a pharmacist who has already undergone the training as part of their formal educational program. Pharmacist counseling services will be covered by Maryland Medical Assistance Program, Maryland Children's Health Program and commercial payers. MPhA advocated strongly to maintain payment provisions. The bill is effective July 2017, regulations must be promulgated on or before September 2018. Pharmacists may begin prescribing after January 1, 2019.

Pharmacy Interns

Establishes an exemption from the requirement to register as a pharmacy technician for a pharmacy student who is currently completing the first year of a professional pharmacy education program.

Medication Synchronization

Requires carriers that provide coverage for prescription drugs, including through a PBM, to allow and apply a prorated daily copayment or coinsurance amount for a partial supply of a prescription drug dispensed by an in-network pharmacy, with some restrictions: 1) best interest of the patient; 2) the prescription is for more than three months; 3) the patient requests; 4) the prescription is not a Schedule II controlled dangerous substance; and 5) the supply and dispensing of the drug meet specified prior authorization and utilization management requirements.

Medication Affordability

Two bills were introduced during the session: one focused on price gouging, and the other on transparency. In the end the price gouging bill was passed. The bills were in response to national attention on soaring drug costs. Stakeholders leading this charge included Maryland's Attorney General and a host of health and patient advocate stakeholders. Its passage is the first of its kind in the nation. The legislation is limited to generic and off-patent drugs that experience "unconscionable" price increases. The attorney general would be authorized to take action if a manufacturer raises the cost of a drug to a level defined as unjustifiable. This legislation was in line with the medication affordability policy passed by the MPhA House of Delegates in 2016.

Expedited Partner Therapy

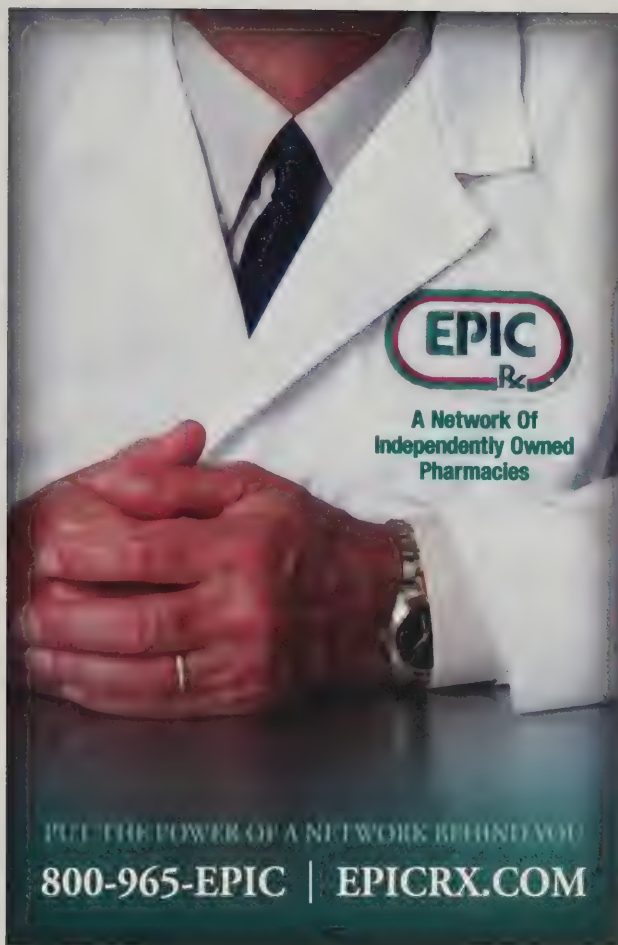
Authorizes a licensed pharmacist to dispense antibiotics therapy prescribed to any sexual partner of a patient diagnosed with chlamydia, gonorrhea or trichomoniasis under the state's expedited partner therapy (EPT) protocols. This had previously been a pilot program in Baltimore. Efforts were made to include pharmacists' liability protection for dispensing EPTs; these amendments were denied by bill sponsors.

Opioid Epidemic

House Opioid Workgroup reviewed more than 30 proposed bills and incorporated the concepts in the Heroin and Opioid Prevention Effort (HOPE) and Treatment Act of 2017. The bill eliminates requirements for patients/caregivers to have Overdose Response Program certificates in order for pharmacists to dispense naloxone; guidelines to be established for co-prescribing naloxone. Healthcare providers with prescriptive authority may prescribe naloxone under certain conditions; expands scope of who can issue standing orders.

OTHER PBMs

There were several PBM-related bills introduced during the session that sought to remove retroactive DIR-fees, clarify definition of specialty drugs, and allow pharmacists to engage in conversation with patients when PBMs reimburse less than the cost of the drugs. All the bills were withdrawn during the session. However, the concerns that were brought before the General Assembly and the ensuing discussions between pharmacists, PBMs, insurers and managed care providers garnered enough attention that a summer study session was convened. The summer study session is being led by the Maryland Insurance Administration. The first meeting was held in early April. The intent is to address issues



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related to specialty drugs, network restrictions, reimbursements that do not cover acquisition costs, perceived retribution against pharmacists that file appeals, among other issues and bring some type of resolution.

Biosimilars

Legislation clarifying how interchangeable biosimilars will be handled in Maryland was passed. MPhA fought to remove interchangeable notification requirements. The bill was amended to allow for the notifications of substitutions to be made by various means of communication to the prescriber and only for the first time.

Single Dispensing or 30-to-90 Day Conversion

MPhA supported the single dispensing bill as another tool in the medication adherence toolbox. The bill did not pass, but would have allowed pharmacists to convert a 30-day prescription with two refills to 90-day single dispensing, without seeking authorization from the physician. The amended bill included some exceptions related to contraceptives and Schedule II drugs. The bill was ultimately withdrawn as consensus could not be reached between pharmacy stakeholders and the psychiatric community.

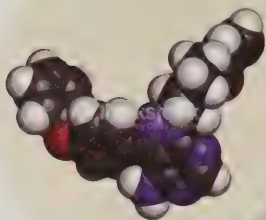
Strong Opposition

There were other bills that MPhA lodged significant opposition and were able to get bills withdrawn or an unfavorable report by the committee of jurisdiction. Those bills were related to physician's assistant dispensing; requirements for lockable vials; oncologists dispensing; and law enforcement notifications when naloxone is administered, among others.

A comprehensive bill tracking chart is available for members-only under the Advocacy tab at www.marylandpharmacist.org. ●

Second Quarter 2017: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH



1992

- Oncologic pharmacy recognized as a specialty by BPS.
- Pharmacy sales in the US totaled approximately \$77.8 billion dollars. This expanded to almost \$154 billion in 2002.



1967

- *Drug Intelligence*, later retitled to *Drug Intelligence and Clinical Pharmacy* and more recently *Annals of Pharmacotherapy*, inaugurated by editor and founder Donald Francke.

1942

- American Society of Hospital Pharmacists (ASHP), now the American Society of Health-System Pharmacists, formed with 153 charter members.



1892

- Formation of the Utah Pharmacists Association

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Management of Acne Vulgaris

Review of Drug Therapy and the Role of the Pharmacist

Melissa Fiscus, PharmD Candidate 2017, Jill A. Morgan, PharmD, BCPS, BCPPS, Neha Sheth Pandit, PharmD, AAHIVP, BCPS
University of Maryland School of Pharmacy

Pharmacist Learning Objectives

After completing this activity, the participant will be able to:

1. Explain the prevalence and disease burden of acne vulgaris in the United States and list the most common causative organism(s).
2. State the efficacy, mechanism of action, and role of medications used in the management of acne vulgaris.

3. Describe three ways in which pharmacists can contribute to the appropriate management of acne vulgaris.

2. Identify medications used to treat acne vulgaris and describe how they work.

Pharmacy Technician Learning Objectives

After completing this activity, the participant will be able to:

1. Describe prevalence and disease burden of acne vulgaris in the United States.

Key Words

- Acne vulgaris
- Isotretinoin
- Benzoyl peroxide

Introduction

Acne vulgaris is a common skin disease that is especially prevalent in adolescents and young adults. It has been estimated that up to 50 million individuals in the United States have acne, and acne affects 85% of people between 12–24 years of age.¹ While there is no mortality associated with acne, many individuals experience physical and psychosocial morbidities, including permanent scarring, depression, anxiety, and poor self-esteem.² The direct costs associated with the treatment of acne vulgaris was estimated to be \$2.5 billion, and the true cost could be as high as \$3 billion per year in terms of treatment and loss of productivity.³ The purpose of this article is to review the current recommendations for the treatment of acne vulgaris based on the recently released guidelines from the American Academy of Dermatology (AAD).

Acne Pathogenesis

Acne vulgaris is defined as a chronic inflammatory dermatosis which causes open or closed comedones (blackheads and whiteheads) and inflammatory lesions.² Acne develops in the pilosebaceous unit, a hair

follicle in the skin that is connected to an oil gland (sebaceous gland).⁴ The hair, sebum (oil), and skin cells that are present in the follicle may produce a plug, which prevents sebum from reaching the surface of the skin through a pore. The mixture of oil and cells allows bacteria to grow in the plugged follicle.⁵ The most common bacterium implicated in acne is *Propionibacterium acnes* (*P. acnes*), a gram-positive anaerobic rod. When the wall of the plugged follicle breaks down, sebum, skin cells, and bacteria spill into the nearby skin, leading to the formation of pimples.⁵

Classification of Acne

Determining the severity of acne is key to selecting an appropriate regimen. Unfortunately, there is no universally agreed-upon grading system for the classification of acne. The AAD recommends that clinicians use a consistent classification system to make treatment decisions and to assess response to therapy.² These classification systems should assess the number and type of acne lesions, sites where acne is located, and the presence of any scarring. In addition, the AAD does not

recommend routine microbiologic or endocrinologic testing for the majority of patients with acne.² Full treatment recommendations for acne vulgaris can be found in **Table 1**.

Topical Therapies for the Treatment of Acne Vulgaris

There are four main categories of acne treatments: topical therapies, systemic antibiotics, hormonal therapies, and oral isotretinoin. Of the four categories, topical therapies contain the most diverse products and are available over-the-counter or by prescription. Topical therapies can be used to treat mild to severe acne, and can be used as monotherapy or in combination. Common topical therapies include benzoyl peroxide, topical antibiotics (clindamycin, erythromycin), topical retinoids (tretinoin, adapalene, tazarotene), azelaic acid, dapsone, and salicylic acid.²

Benzoyl peroxide (BP) is a bactericidal agent with no reported resistance that kills *P. acnes* through the release of oxygen free radicals. BP is available over the counter in strengths up to 10% and can be used as monotherapy or in combination. When used in combination with

other agents, BP enhances results and may reduce the development of antibiotic resistance. However, BP therapy is limited by staining or bleaching of fabric, severe skin irritation, and rare contact allergy. Patients initiating BP therapy should gradually increase the amount of product used and frequency of application to reduce skin irritation. Results of BP therapy can be noted in as soon as five days.²

Another available **topical modality** is topical antibiotics, including **clindamycin** and **erythromycin**. These antibiotics accumulate in the follicle and work through anti-inflammatory mechanisms and antibacterial effects to treat acne. Currently, clindamycin 1% gel or solution is preferred over topical erythromycin for acne therapy due to the development of erythromycin-resistant *Staphylococcus* and *P. acnes*. Topical antibiotics are available with a prescription, are generally well tolerated, and should only be used in combination with BP to increase efficacy and reduce antibiotic resistance.²

Topical retinoids are vitamin A derivatives that are available with a prescription for the treatment of acne. Presently, there are three agents available: **tretinoin**, **adapalene**, and **tazarotene**. Each retinoid binds to a different retinoic acid receptor, which confers slight difference in activity, efficacy, and tolerability. Topical retinoids enhance any topical acne regimen, prevent the formation of clogged pores, and maintain clearance after discontinuation of oral therapy. Retinoid use can be limited by dryness, peeling, redness, or irritation of skin, and photosensitivity. To avoid issues with photosensitivity, pharmacists can counsel patients to apply topical retinoids at night. In addition, tretinoin cream or gel may be inactivated by the coadministration of BP. Patients should be counseled to apply these two agents at different times. There is no such interaction with tretinoin microsphere formulation, adapalene, or tazarotene.²

Azelaic acid 20% (Azelex®) is a comedolytic, antibacterial, and anti-inflammatory agent that is

available with a prescription for the treatment of acne vulgaris. This agent is mildly effective and used mostly in patients with sensitive skin, or patients with post-inflammatory hyperpigmentation seen most commonly in patients with darker skin (Fitzpatrick skin types IV or greater) due to a lightening effect.² Azelaic acid's efficacy increases as the dose increases, but burning has been reported at higher concentrations.⁶ It should be noted that no matter the dose, azelaic acid is not as effective as BP or topical retinoids.

Dapsone 5% gel is a sulfone agent that is also used for the treatment of acne vulgaris. The mechanism of action is poorly understood, but topical dapsone showed modest to moderate efficacy in the reduction of inflammatory lesions in clinical trials. Furthermore, topical dapsone has greater efficacy in females as compared to male or adolescent patients. Topical dapsone can be oxidized by the coadministration of BP, causing an orange-brown discoloration of the skin.² It should be noted that this discoloration is not

TABLE 1
Treatment guidelines for the management of acne vulgaris

	Mild	Moderate	Severe
1st Line Treatment	Benzoyl peroxide (BP) -or- Topical retinoid -or- Topical combination therapy	Topical combination therapy -or- Oral antibiotic + topical retinoid + BP -or- Oral antibiotic + topical retinoid + BP + topical antibiotic	Topical combination therapy + oral antibiotic -or- Oral isotretinoin
Alternative Treatment	Add topical retinoid or BP (if not on already) -or- Consider alternate retinoid -or- Consider topical Dapsone	Consider alternate combination therapy -or- Consider change in oral antibiotic -or- Add combined oral contraceptive or oral spironolactone (females) -or- Consider oral isotretinoin	Consider change in oral antibiotic -or- Add combined oral contraceptive or oral spironolactone (females) -or- Consider oral isotretinoin

permanent and can be brushed or washed off.

Salicylic acid is a comedolytic agent available over-the-counter in 0.5% and 2% strengths for the treatment of acne vulgaris. While it is generally well tolerated, salicylic acid is less efficacious than BP and topical retinoids, and clinical trials demonstrating the efficacy of salicylic acid are limited.² Salicylic acid can irritate the skin, which can lead to erythema, peeling, and exacerbations of inflammatory lesions in some individuals.⁶

Systemic Antibiotics for the Treatment of Acne Vulgaris

Systemic antibiotics are commonly used in the treatment of moderate to severe inflammatory acne in combination with topical therapies. There is evidence supporting the efficacy of tetracyclines (doxycycline and minocycline), macrolides (erythromycin and azithromycin), penicillins, cephalosporins, trimethoprim/sulfamethoxazole (TMP/SMX), and trimethoprim.² While systemic antibiotics are effective for many patients, monotherapy with oral antibiotics is strongly discouraged due to the development of antibiotic resistance. Antibiotic usage should be limited to the shortest possible duration, ideally 3–4 months or less, to prevent the development of complications including inflammatory bowel disease, pharyngitis, and *Clostridium difficile* infection.² Combining systemic antibiotics with topical therapies has led to decreased antibiotic use, decreased antibiotic resistance, and continued efficacy months after discontinuation of systemic antibiotics.

Tetracyclines are considered first-line therapy for moderate to severe acne unless contraindicated. Contraindications to tetracycline therapy include pregnancy, age ≤ 8 , or allergy. Tetracyclines inhibit protein synthesis by binding to

the 30S subunit of the bacterial ribosome. Previous guidelines recommended minocycline as a superior agent to doxycycline; however, a recent Cochrane review determined that minocycline is effective, but not superior to other antibiotic therapies.⁷ The most common side effect noted with tetracyclines is photosensitivity, particularly with doxycycline. In addition, doxycycline is more often associated with dose-dependent gastrointestinal symptoms, while minocycline has been associated with tinnitus, dizziness, and tooth discoloration at higher doses.²

If a patient cannot use a tetracycline, **macrolide antibiotics** are an effective alternative agent.

Macrolides, such as erythromycin and azithromycin, work to treat acne vulgaris by binding to the 50S subunit of the bacterial ribosome. Azithromycin has been the macrolide most commonly studied, and dosing regimens ranging from three times a week to four days a month have shown to be effective after 2–3 months of therapy. Macrolides most commonly cause gastrointestinal symptoms, and erythromycin in particular has a higher incidence of abdominal discomfort, diarrhea, and nausea.²

Another option for patients with a contraindication to tetracyclines are **penicillins** or **cephalosporins**. These antibiotics treat acne vulgaris by inhibiting bacterial cell wall synthesis. Very little data exists to support the use of these medications; however, a small retrospective chart review with cephalexin indicated a majority of patients showed some clinical improvement.⁸ Common side effects associated with penicillin or cephalosporin therapy include hypersensitivity reactions and gastrointestinal disturbances.²

TMP/SMX and **trimethoprim** have also been used to treat acne vulgaris, although the

data supporting their use is limited to mostly case reports. Sulfamethoxazole blocks bacterial synthesis of folic acid and trimethoprim is a folic acid analog that inhibits dihydrofolate reductase. Together, these two agents treat acne vulgaris by inhibiting cell division. Side effects of TMP/SMX include gastrointestinal upset, photosensitivity, and rare drug eruptions such as Stevens-Johnson syndrome and toxic epidermal necrolysis.² The use of TMP/SMX should be avoided in pregnancy due to risk of congenital malformations if used in the 1st trimester and risk of kernicterus if used close to time of delivery.

Hormonal Therapies for the Treatment of Acne Vulgaris

Combination oral contraceptives (COCs) are prescription medications used for contraception that can also be used for the treatment of mild to moderate acne vulgaris. COCs contain an estrogen and a progestin and treat acne through antiandrogenic effect. Currently, there are four COCs approved by the FDA for acne treatment: ethinyl estradiol/norgestimate, ethinyl estradiol/drospirenone, ethinyl estradiol/drospirenone/levomefolate, and ethinyl estradiol/norethindrone acetate/ferrous fumarate. It's important to note that COCs are only approved for acne treatment in women who also desire contraception, and use of COCs for acne should be avoided within two years of the onset of menses or in patients who are younger than 14 years of age.

A recent Cochrane review analyzed the effect of COCs on acne in women and concluded that all COCs reduce acne, but there is no COC that is consistently superior to other agents.⁹ There are a wide variety of side effects associated with COCs, including cardiovascular risks and possible increased risk

of breast and cervical cancer. The use of a COC increases the risk of venous thromboembolic events (VTEs) for all women; however, myocardial infarction (MI) or stroke is uncommon among healthy women of reproductive age. Patients should be counseled that acne reduction with COCs will take time, and significant acne reduction might not be appreciated until three months of therapy.²

Another hormonal agent that is used for the treatment of acne is **spironolactone**. Spironolactone is an aldosterone receptor antagonist that decreases testosterone production and inhibits the binding of testosterone to androgen receptors through antiandrogen activity.² Spironolactone is generally well tolerated, and common side effects include diuresis, menstrual irregularities, breast tenderness, and breast enlargement. While frequently used in practice, spironolactone has not been approved by the FDA for the treatment of acne. A recent Cochrane review examined the small number of available studies and concluded that there was insufficient evidence to support the use of spironolactone in the treatment of acne.¹⁰ Despite this, AAD guidelines still acknowledge the use of spironolactone in select women based on available evidence, experience, and expert opinion.²

Oral Isotretinoin for the Treatment of Acne Vulgaris

Isotretinoin is an isomer of retinoic acid and has been used for more than 30 years to treat severe acne

or moderate acne that is treatment-resistant. Isotretinoin is highly effective and its use results in reduced sebum production, decreased number of acne lesions, and minimal acne scarring. When dosing isotretinoin, the AAD recommends a cumulative dose regimen for severe acne (120 to 150 mg/kg total) and a low-dose regimen for moderate acne. (0.25 to 0.4 mg/kg/day) However, intermittent dosing of isotretinoin is not recommended due to decreased efficacy and higher relapse rates.²

Before initiation of isotretinoin therapy, there are many details prescribers and patients should understand. First, isotretinoin is highly lipophilic and is best absorbed when taken with food, preferably a high fat meal. Recently, manufacturers have released new formulations which encase isotretinoin with lipid agents and allow the medication to be taken on an empty stomach.¹¹ It is important that patients know which formulation they are taking and understand the appropriate way to take their medication.

In addition, there are side effects to isotretinoin that require laboratory monitoring. Isotretinoin can cause an increase in liver function enzymes tests, triglycerides, and serum cholesterol. All patients receiving isotretinoin should receive laboratory monitoring of liver function and lipid panel tests at baseline and at biweekly intervals until treatment response is established. Other common side effects of isotretinoin therapy include arthralgia, musculoskeletal pain, and dry eyes. These side effects are

temporary and fully resolve after discontinuation of the drug.²

Furthermore, isotretinoin is highly teratogenic and can lead to severe birth defects if taken while pregnant. Every patient (male and female) receiving isotretinoin is required to enroll in the risk management program, "iPLEDGE," prior to starting therapy. The iPLEDGE program provides education about the teratogenicity of isotretinoin, requires female participants to undergo

routine pregnancy tests before, during, and after therapy, and requires female patients to use two contraceptive methods for at least one month before treatment, during treatment, and one additional month after finishing treatment.¹² Despite this, nearly 600 isotretinoin-exposed pregnancies occurred between the years of 2008–2011.¹³ Therefore, every woman of child-bearing age should continue to be counseled about the risks of isotretinoin therapy and the importance of contraception throughout their treatment.²

Role of the Pharmacist

With the prevalence of acne in all patient populations and the availability of over-the-counter treatments, pharmacists are key to appropriate management of acne vulgaris. Pharmacists can determine if self-treatment is appropriate, recommend a suitable regimen, counsel on potential side effects, and provide non-pharmacologic recommendations as necessary.

Continued on page 23

CONTINUING EDUCATION QUIZ



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Directions for taking this issue's quiz:

This issue's quiz on **Management of Acne Vulgaris: Review of Drug Therapy and the Role of the Pharmacist** can be found online at www.PharmCon.com.

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Note: If this is not the first time you are signing in, just scroll down to Homestudy/OnDemand CE Credits and select the quiz you want to take.

TABLE 2
Counseling Information for First-Line Therapies

Drug	Indication	Clinical Pearls
Benzoyl peroxide	Mild to Moderate AV	• No reported resistance • Can be used as monotherapy or in combination • Adverse effects include staining of fabric, concentration-dependent irritation, photosensitivity, and rare hypersensitivity reactions
Topical clindamycin	Mild to Moderate AV	• Preferred over topical erythromycin due to erythromycin resistance • Must be used in combination with benzoyl peroxide
Topical tretinoin	Mild to Moderate AV	• Cream and gel formulations are inactivated by the co-administration of benzoyl peroxide • Adverse effects include dryness, peeling, redness, or irritation of skin, and photosensitivity • Due to case reports of congenital malformations, other agents are preferred during pregnancy.
Topical adapalene	Mild to Moderate AV	• Adverse effects include dryness, peeling, redness, or irritation of skin, and photosensitivity • Due to case reports of congenital malformations, other agents are preferred during pregnancy.
Topical tazarotene	Mild to Moderate AV	• Adverse effects include dryness, peeling, redness, or irritation of skin, and photosensitivity • Due to case reports of congenital malformations, use in pregnancy is contraindicated.
Oral doxycycline	Moderate to Severe AV	• Use contraindicated in pregnancy, age <8, or allergy • Adverse effects include photosensitivity, and gastrointestinal symptoms
Oral minocycline	Moderate to Severe AV	• Use contraindicated in pregnancy, age <8, or allergy • Adverse effects include photosensitivity, tinnitus, dizziness, and hyperpigmentation
Combination oral contraceptives	Moderate to Severe AV	• Use only in female patients who also desire contraception • Use should be avoided within 2 years of the onset of menses or in patients age <14 • Adverse effects include VTE, MI, stroke, and breast/cervical cancer
Oral isotretinoin	Severe or Treatment-resistant Moderate AV	• Best absorbed when taken with food, preferably a high-fat meal • All patients must enroll in iPLEDGE prior to initiation of therapy • Female patients are required to undergo routine pregnancy tests before, during, and after therapy due to teratogenicity. • All patients must use 2 contraceptive methods while on therapy

TABLE 3
Summary of Key Recommendations

- Topical benzoyl peroxide and topical retinoids are effective first-line agents that can be used as monotherapy for the treatment of acne.
- Monotherapy with topical or systemic antibiotics is not recommended due to the risk of bacterial resistance.
- Systemic antibiotic use should be limited to the shortest possible duration.
- Combined oral contraceptives (COC) are effective for treatment of acne in females but should only be used if patients desire contraception.
- Oral isotretinoin is recommended for severe acne or moderate acne that does not respond to other therapies.
- All patients treated with isotretinoin must adhere to the iPLEDGE risk management program and receive routine laboratory monitoring.

PATIENT CASE

Ms. Martin is a 17-year-old high school student who presented to your clinic for a requisite physical for her high school volleyball team. During the visit, Ms. Martin stated that she had been bothered by facial acne for the past 2 years. She described facial breakouts that began gradually, varied in severity, and never completely cleared. Ms. Martin has been washing her face daily with soap and warm water but has not tried any acne products yet. Ms. Martin is not currently taking any other medications and denies any allergies. A physical examination revealed a healthy young woman with 10 non-inflammatory closed comedones located on her chin and forehead. She has no lesions on her chest, back, or shoulders. Additional history and physical examination findings were noncontributory.

CE QUESTIONS

1) What agent would you recommend to Ms. Martin at this time?

- A) Topical dapsone
- B) Oral doxycycline
- C) Topical benzoyl peroxide
- D) Topical erythromycin

2) What counseling would you provide Ms. Martin about the use of benzoyl peroxide for the management of acne?

- A) Benzoyl peroxide should not be used as monotherapy due to the development of resistance
- B) Side effects of benzoyl peroxide include skin irritation and staining or bleaching of fabric
- C) Benzoyl peroxide has greater efficacy in females as compared to male or adolescent patients
- D) It can take 14 days before you see results of benzoyl peroxide therapy

3) What course of action do you recommend for Ms. Martin at this time?

- A) Add on a topical retinoid
- B) Add on ethinyl estradiol/norgestimate
- C) Change to oral doxycycline
- D) Change to oral isotretinoin

Answers on page 24

While many patients with mild to moderate acne can successfully self-treat with non-prescription products, patients with severe acne, patients with persistent acne despite appropriate use of non-prescription therapies, and patients with exacerbating factors (e.g. drug-induced acne or irritation-induced acne) should be referred to a physician for a more complete evaluation of their acne.¹⁴ For all acne patients however, pharmacists are uniquely positioned to educate on prescription and non-prescription acne therapies. A compilation of

important counseling points for the most common acne therapies can be found in **Table 2**.

In addition to education on pharmacologic modalities, pharmacists can provide patients with non-pharmacologic recommendations. To prevent the formation of acne, patients should avoid exposure to irritating factors such as dirt, dust, chemical irritants, tight-fitting clothes, or helmets. Limiting frequent handling of skin and maintaining adequate hydration can also reduce or minimize the

formation of acne flare-ups. Patients with existing acne lesions should gently wash their face with a mild cleanser twice daily and avoid touching or squeezing pimples, as this can lead to worsening acne and scarring.¹⁴

Furthermore, many patients often have questions about whether certain foods lead to the formation or worsening of acne. Emerging evidence has suggested that high glycemic index diets could be associated with acne. In a 2007 randomized controlled trial,

subjects assigned to follow a low glycemic index diet had significant improvement in acne severity in addition to a reduction in weight and BMI.¹⁵ However, this study was limited by its small sample size of 23 patients and the fact that both cohorts lost weight. A similar trial conducted in 2012 found that subjects randomized to the low glycemic index diet also had improved acne severity, although

there was no change in weight or BMI.¹⁶ Given the current data, the AAD does not recommend any specific dietary changes for the management of acne.²

Conclusion

Acne vulgaris is a common skin disorder affecting patients of all ages. There are many first-line agents for the treatment of acne, including topical therapies, oral antibiotics,

combination oral contraceptives, and oral isotretinoin. The selection of an appropriate agent depends largely on acne severity and patient preference. Due to the wide variety of non-prescription and prescription acne products available, pharmacists are a great resource for triage, suitable product selection, and education on pharmacologic and non-pharmacologic therapies for the management of acne vulgaris.

CE QUIZ ANSWERS

1. **C.** Benzoyl peroxide is an effective first-line agent that can be used as monotherapy for the treatment of acne. Topical dapsone would be appropriate for mild acne, but only if first-line options haven't worked. Topical erythromycin should not be used as monotherapy due to the development of erythromycin-resistant *Staphylococcus* and *P. acnes*. Finally, oral doxycycline is not a preferred option for patients with mild acne and should not be used as monotherapy.
2. **B.** Benzoyl peroxide frequently causes skin irritation and staining or bleaching of fabric. All patients

starting BP therapy should be counseled about these side effects. Benzoyl peroxide can be used as monotherapy, may reduce the development of antibiotic resistance, has equal efficacy in males and females, and patients can see results in five days.

Over the course of four months, Ms. Martin's acne has increased to 20 lesions on her chin, forehead, and cheeks. She has been using benzoyl peroxide but has not seen any improvement. Ms. Martin went to see a dermatologist who diagnosed her with moderate acne and referred her to you for a recommendation.

3. **A.** One of the first line recommendations for moderate acne is topical combination therapy. Ms. Martin should try a first-line topical combination therapy before selecting an alternative regimen, such as a combined oral contraceptive. Oral doxycycline could be used to treat moderate acne, but not as monotherapy. Oral isotretinoin is only indicated for severe acne or moderate acne that is treatment resistant.

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Executive Director's Message

As I reflect on our most recent accomplishments, whether it is our newly achieved prescriber status for contraceptives (the first state on the East Coast and the 4th in the nation!) or our other legislative successes, the word PARTNERSHIP comes to mind.

While pharmacists have the education, experience and statistics on our side, our ongoing success hinges on the partnerships we forge with pharmacy schools, pharmacy technicians, elected leaders, pharmacists across practice settings and of course patients. We cannot advance pharmacy practice alone.

We must continue to work with all aspects of the pharmacy community and healthcare stakeholders to protect prescriptive drugs as an essential health benefit and protect the funding that provides the foundation for advances in medications, evidence-based prescribing and treatment of chronic diseases.

We must continue to forge relationships with our elected leaders. When members of the General Assembly and Congress understand the value pharmacists bring to the healthcare team and our ability to provide increased healthcare access, they fight for us. They work to ensure you are able to practice at the height of your education AND receive appropriate compensation. They are also more open to supporting strategic roles

for pharmacists to mitigate crises in Maryland like the spread of sexually transmitted diseases and opioid overdoses.

Partnerships take time and resources. As MPhA continues to find new partnerships to support practice advancement, you are encouraged to continue to invest your time and your resources in MPhA. Encourage your colleagues to do the same. Your effort and support yield results.

I look forward to seeing you June 23-26 at The Wisp Resort in McHenry, MD for MPhA's 135th Annual Convention. Our theme, *Taking Pharmacy to New Heights*, will explore the evolving role of pharmacy in addressing today's healthcare challenges. Sessions will explore:

- Opioid epidemic from a clinical perspective and pharmacist's role due to legislative changes in MD
- Updates on new drugs
- USP 800
- 2017 legislation
- Communication strategies for patient safety
- Pharmacy robbery and fraud prevention
- Management of depression
- COPD management
- Technician- focused sessions on pharmaceutical calculations



- Financial planning sessions for new practitioners and more seasoned professionals
- Oral chemotherapy in outpatient settings

MPhA is taking pharmacy to new heights by providing pharmacists and pharmacy technicians with relevant and timely CE activities. We also look forward to having a good time, welcoming new leadership and saluting those who have served MPhA and the pharmacy community well.

See you at Wisp! ●

Respectfully,

Aliyah N. Horton, CAE
Executive Director



MPhA

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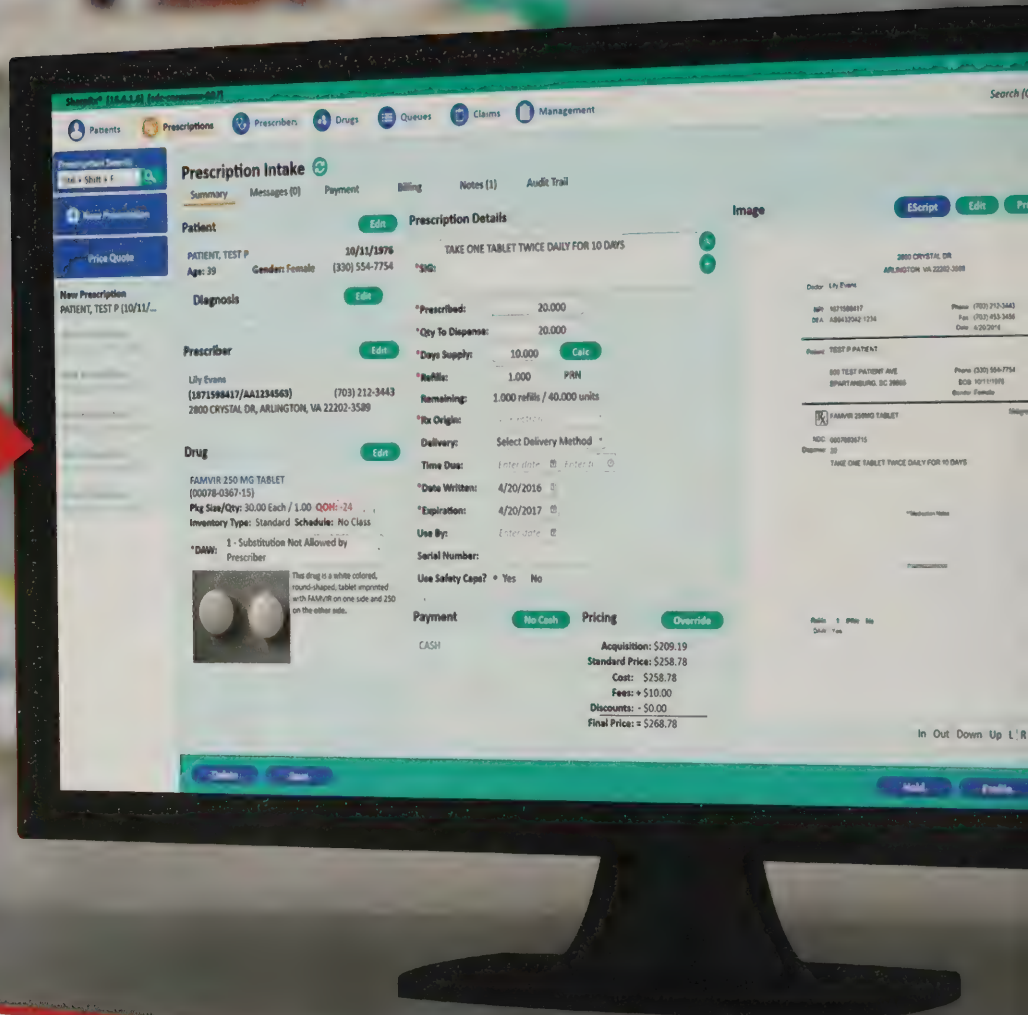
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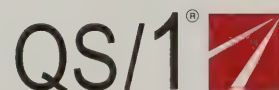
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Congratulations to all MPhA's
2017 award winners!

MPhA News

Highlights of 135th Annual
Convention

**Congratulations to
2017 Graduates**

And congratulations to the 2017
MPhA Outstanding Student
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**Legislative and Policy
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Changes in opioid prescribing,
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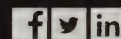
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President's Pad

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Dear Fellow MPhA Members:

Happy Summer! We have just returned from the 135th MPhA Annual Meeting at the Wisp Resort, and I, like many of those in attendance, have come back refreshed by all the educational topics, networking and camaraderie. We also celebrated the practice, service and leadership accomplishments of our members. It is amazing to be able to honor our colleagues and friends for the work they do every day, and it is even more remarkable that these same people share their time and efforts with MPhA. Congratulations to all the award winners!

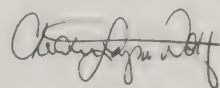
We had an amazing meeting, and one that has wrapped up an action packed year for MPhA with all the events and practice-changing bills passed during this year's legislative season. The Board of Trustees and committee chairs have done amazing work this year to help realize the vision of Kristen Fink's presidency by enhancing our engagement with student pharmacists, and also continue the mission of MPhA.

As the incoming MPhA president, my vision for this coming year is for our membership to be "Provider Ready." Our members have made many efforts to advocate for provider status, and every practice bill that is passed brings us even closer to pharmacists being recognized as providers a reality. Along with all our advocacy work, we must also ensure that we are advancing our knowledge, skills and abilities to provide patient care in all the settings that we practice and to also understand the factors that impact our ability to provide patient care. I will work with the Board of Trustees, our committees and members to provide resources and education so we are ready for the responsibility of provider recognition.

We cannot do this work alone, and I thank many of you who have served as an advocate for pharmacy and for providing the important patient care you already do in your practices. I also thank you for sharing your expertise, guidance and input with us as we work to strengthen our outreach and resources to our members and the Maryland pharmacy community. I invite you to continue your engagement with MPhA, and to also bring others along with you. We can do so much work when we support each other, and understanding our practice and advocacy needs at minimum will help support our provider status efforts. We look forward to having you join us for our numerous programming and networking opportunities this year. Please be sure to check out the Monday Message, the MPhA website, the MPhA journal, MPhA Facebook and Twitter accounts, and finally our regular meetings to keep up to date with what we've got in store for you!

I sincerely look forward to serving as president of MPhA this year and hope that you will join us in becoming "Provider Ready." ●

Kindest regards,



Cherokee Layson-Wolf
President

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Visit MPhA Website for more details

September 19

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September 28

Public Board of Trustees Meeting — MPhA Headquarters, Columbia, MD

October 12

Medication Safety CE — MPhA Headquarters, Columbia, MD

October 26

Public Board of Trustees Meeting — MPhA Headquarters, Columbia, MD

November 16

Public Board of Trustees Meeting — MPhA Headquarters, Columbia, MD

December 14

Public Board of Trustees Meeting and Holiday Party — MPhA Headquarters, Columbia, MD

Phi Lambda Sigma & MPhA Foundation Partner for MPJE Study Strategies and Test Taking Tips

On a bright and early Saturday June morning, Phi Lambda Sigma members hosted 42 pharmacists and student pharmacists preparing for the MPJE at Notre Dame's Knott Auditorium with a common goal in mind: improve the Maryland MPJE first-time pass rate. Among other issues that negatively affect the pharmacy workforce are declining NAPLEX and MPJE pass rates across the nation. With the 2017 NAPLEX increasing to a six-hour, 250-questions exam, and Maryland MPJE first-time pass rates below the national MPJE average, Maryland's new graduates, residents, and transferring pharmacists face a greater challenge entering Maryland practice.

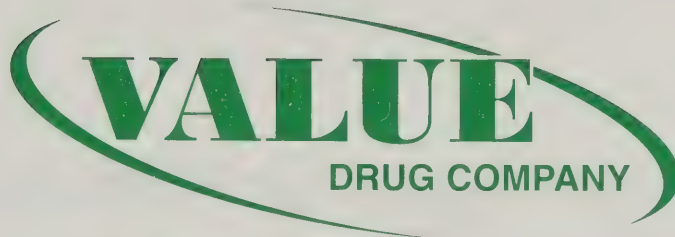
The three Schools of Pharmacy all experienced MPJE first-time pass rate declines during 2014-2016 (see table). This suggests that the problem lies not with students, instructors, or courses, but rather with the Maryland MPJE itself.



MPJE 2014–2016 Passing Rates for Graduates per Pharmacy School						
	2014		2015		2016	
	1st Time Attempts	Pass Rate	1st Time Attempts	Pass Rate	1st Time Attempts	Pass Rate
University of Maryland Baltimore	106	94.34%	109	95.41%	109	82.57%
University of Maryland Eastern Shore	39	87.18%	31	90.32%	31	51.61%
Notre Dame of Maryland University	37	89.19%	43	79.07%	35	77.14%

Source: NABP <https://nabp.pharmacy/wp-content/uploads/2017/02/2016-MPJE-Pass-Rates.pdf>

Continued on page 8



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Member Mentions & News You Can Use

Past President Elected to APhA Board of Trustees

Past MPhA President Magaly Rodriguez de Bittner, PharmD, FAPhA was elected to the APhA Board of Trustees! The new Trustees will be installed at the APhA Annual Meeting in Nashville in March 2018. Congratulations Magaly!



New Maryland Board of Pharmacy Commissioners

Congratulations to the MPhA members who joined the MPhA Board of Pharmacy in May: Rhonda M. Toney as an At-Large Representative and Neil B. Leikach as an Independent Representative.

MPhA Member in the News

MPhA Member Matthew Balish recently conducted two interviews with his local cable channel's Focus on Health series. The two interviews, *Medication Disposal and Immunizations & Older Adults*, can be found on the Focus on Health YouTube channel.

MPhA Member Honored by Baltimore County Department of Aging

Congratulations to George Garmer, owner of Halethorpe and Independent Pharmacies, for being honored as the Baltimore County Department of Aging Business Partner of the Year.



In Memoriam SAMUEL LICHTER

The Maryland pharmacy community lost a friend, colleague and mentor, Samuel Lichter on April 17, 2017. Sam was a Past President and remained active in the MPhA. In acknowledgement of his contributions, the Past President's Council posthumously honored him as MPhA's 2017-2018 Honorary President. ●



MPJE Study Strategies *continued from page 6*

Several detrimental effects from this phenomenon include delays in employment, higher employee and employer costs and ACPE implications for the state's three pharmacy schools.

In response, Phi Lambda Sigma chapters from UMB, NDMU, and UMES partnered with the MPhA Foundation to offer a course titled "MPJE Study Strategies and Test

Taking Tips" to supplement and optimize prior learning. Developed and taught by Beta Lambda chapter alumnus Andrew York, Pharm.D., J.D., the course augments the fact-based law courses emphasizing efficiency and effectiveness of study strategies and testing skills. The Phi Lambda Sigma chapters are committed to continuing to offer this course annually.

True to Albert Einstein's quote, "In the middle of difficulty lies opportunity," Phi Lambda Sigma and the MPhA Foundation partnered on an opportunity to address a specific need for those seeking to enter pharmacy practice in Maryland. With MPhA's support, the three organizations proved the value proposition that we are indeed, "better by association."

Graduating Members

Congratulations to all the 2017 PharmD Graduates!

MPhA and the New Practitioners Network look forward to working with you and supporting you as you transition from student to practicing pharmacist.

University of Maryland School of Pharmacy

Sameh Abdelmalak
Larra Achmar
Esther Adenuga
Harrison Akujor
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MPhA Outstanding Student Pharmacist Achievement Award

Congratulations to the following students who were recognized with the MPhA's Outstanding Student Pharmacist Achievement Award. The Award recipients received a crystal award and a \$250 check.



Courtney Lanehart, PharmD, Notre Dame of Maryland University

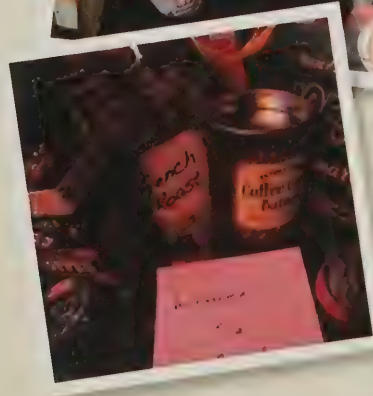


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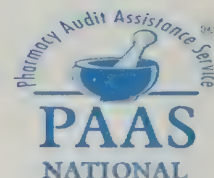


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Rx and the Law | CYBERSECURITY

By Don. R. McGuire Jr., R.Ph., J.D.

This series, *Pharmacy and the Law*, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

Cybersecurity continues to make the news and to be a source of concern for all business owners. The recent WannaCry ransomware attack affected companies and governments in more than 150 countries. Data breaches and cyberattacks also occur in healthcare. In Rhode Island, the car of an employee of the state's largest health network was broken into and a laptop was stolen. The laptop contained sensitive information on about 20,000 of the network's patients. A healthcare provider in Texas had an unencrypted hard drive stolen. The hard drive contained information (e.g., social security numbers, dates of birth, driver license numbers, insurance information, etc.) about its patients going back to 2009. It is critical for pharmacies to assess their data security and take steps to strengthen it.

Stronger regulations are sure to come, but improvements to your data security now will minimize the chances that your pharmacy ends up as your community's lead news story. As an example, the New York Department of Financial Services recently promulgated new rules for cybersecurity of financial institutions.¹ This includes banks, insurance companies, and other financial services institutions. It does not apply to health care organizations or entities. The regulations contain 15 requirements for a cybersecurity program. This article will not review all of them, but will address some that apply to the situations we have already seen.

The regulations require penetration testing and vulnerability assessments. This would mean

at least annual testing of firewalls and other portions of the overall cybersecurity program. This should alert you to any shortcomings in your security and give you the opportunity to remedy them before an incident occurs.

Also required is training and monitoring for your system's users. Training is an integral part of a security program because a leading cause of data breaches is the people using the system. Phishing attacks and similar techniques succeed because they fool a user into allowing unauthorized access to the pharmacy's data.

Encryption is another important tool and New York's regulation is going to require it. The regulation requires that data be encrypted both while being transmitted (such as by e-mail) and also while resting on hard drive. This requirement would help secure data that is physically taken, such as in the stolen laptop or server examples. Many people think to encrypt data while it is in transit, but steps should also be taken while it is being stored.

The regulation also requires that organizations periodically dispose of sensitive information no longer needed for business operations. This will require the organization to assess the need to retain sensitive information and then follow their own policies and procedures to securely dispose of unneeded information. This action may have mitigated the damage done when the hard drive containing seven years of data was stolen in Texas.

The world continues to move toward more virtual and digital realms, so these challenges are

not going away. Dealing with data breaches is expensive. Some studies estimate around \$200 per record affected. For the data of those 20,000 patients on the laptop, this equates to around \$4 million. And this doesn't take into account your reputational damage. The pharmacist-patient relationship is built on trust and data breaches will seriously damage these relationships. Ransomware can also be devastating to your pharmacy. Having your system held hostage until you pay the ransom (or can re-construct your system from back-ups) will, at a minimum, inconvenience your patients. It may cause them to question whether they should share their personal information with you.

There is no reason to wait for a law or regulation to be passed before shoring up your data security. You are already holding sensitive patient information and there are already numerous threats out there in cyberspace. A cyber incident can cause significant financial and reputational damage to your practice. This is not the time to take an ostrich approach to your data security.

REFERENCES

1 23 NYCRR 500.00 to 500.23

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly. ●

135th Annual Convention — Taking Pharmacy to New Heights Highlights

Thank you to Darci Eubank, Sadhna Khatri and the Meeting Planning Committee for putting together a great program of CEs and fun activities! Photos courtesy Albert Ayemor, PharmD Candidate 2018.

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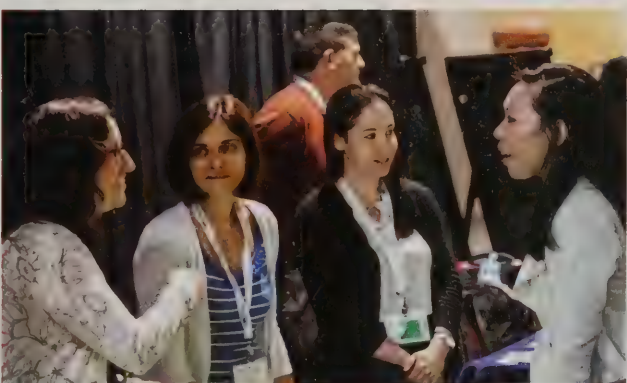
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EVENTS

RECEPTION



EXHIBITION



CRAB FEAST



Check out MPhA's Facebook page for more fun photos from the 135th Annual Convention!

Continued on page 16

EVENTS

TRUSTEES



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BONFIRE



AWARDS LUNCHEON



GENERAL



AWARDS



MPhA Foundation Scholarship Winner
A Alexis Noelle Smith, student, University of
Maryland Eastern Shore School of Pharmacy



MPhA Scholarship Winner: Jessica Wearden,
student, University of Maryland Eastern Shore
School of Pharmacy



MPhA Scholarship Winner: Albert Ayernor,
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AWARDS



Mentor Award Winner: Nicole Culhane, PharmD



Distinguished Young Pharmacist Award Winner: Darci Eubank, PharmD. Sponsored by Pharmacists Mutual Companies.



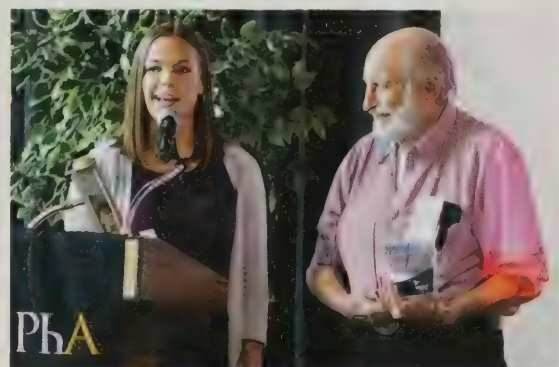
Excellence in Innovation Award Winners: Dixie Leikach, RPh, MBA, FACA (2nd from left) and Neil Leikach, RPh (1st from right). Sponsored by Upsher-Smith Laboratories, Inc. and the MPhA Foundation.



Pharmacist Advocate Award Winner: Chai Wang, PharmMD, BCPs, AE-C. Sponsored by Buy-Sell-a-Pharmacy.



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Generation Rx Champions Award Winner: Jacob Raitt, PhD. Sponsored by Cardinal Health Foundation.



Bowl of Hygieia Award Winner: Cynthia Boyle, PharmD. Sponsored by the American Pharmacists Association Foundation and National Alliance of State Pharmacy Associations.

POLICY ACTIONS

Archived Policy 16. Maryland DHMH Emergency Response

Approved:

1. Emergency Preparedness and Response

MPhA supports and encourages its members and all pharmacists, student pharmacists, and pharmacy technicians all pharmacists to be knowledgeable of their vital role and prepared to respond to local community needs in the event of a public health emergency and to assist on a larger scale by becoming members of the Maryland Responds Medical Reserve Corps as promulgated by the Maryland Department of Health.

For current MPhA Policies visit www.marylandpharmacist.org — About MPhA — Governance — Policies

Proposed By-Law Changes:

In addition, two amendments to the MPhA Bylaws were approved by the House of Delegates. The first amendment adds an elected Trustee seat for a Dean from one of Maryland's three schools of pharmacy. The seat would be voted on by the entire membership. The second amendment clarifies the role of the Resolutions Committee. The amendments must be approved by MPhA members. An electronic ballot was distributed in July.

Continued on page 18

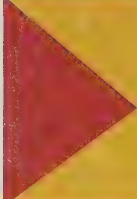
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SAVE THE DATE

136th Annual Convention
Ocean City, MD • June 29 – July 2, 2018

Editorial

Third Quarter 2017: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1992

Jerome Schentag, PharmD, professor of pharmaceutical science at the University of Buffalo, co-inventor of the computer-controlled "smart pill," which can be electronically tracked and instructed to deliver a drug to a predetermined location in the gastrointestinal tract.

1967

- World's First Heart Transplant operation in South Africa by Dr. Christiaan N Barnard and Thomas Starzl performs the first successful human liver transplantation, at the University of Colorado Health Sciences Center.

1942

- Heparin marketed by Upjohn, originated from Johns Hopkins

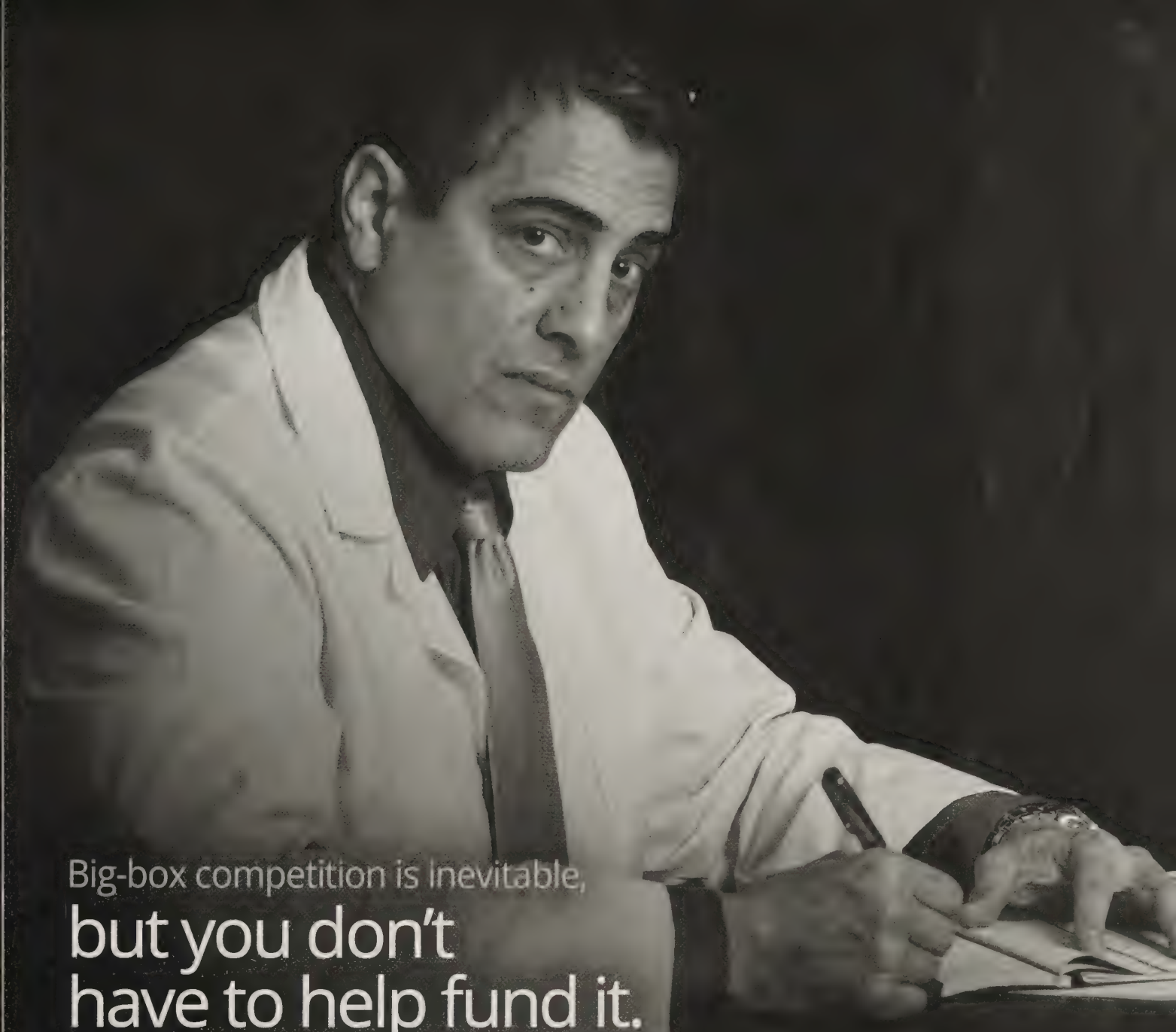
1917

- US enters WW I with a declaration of war on Germany

1892

- The New Jersey College of Pharmacy, now the Ernest Mario College of Pharmacy, founded in Newark.

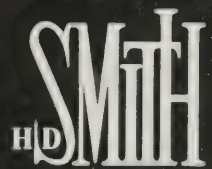
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Antidiabetic Agents

Recent Updates on the Cardiovascular Risks and Benefits

Kathleen J Pincus, PharmD, BCPS, University of Maryland School of Pharmacy

Learning Objectives

After completing this activity, the participant will be able to:

1. Identify which agents used to treat type 2 diabetes have demonstrated positive effects on cardiovascular outcomes since 2008
2. Compare the outcomes that were measured among the relevant clinical trials
3. Given a clinical case for a patient with type 2 diabetes mellitus, determine whether sodium glucose transporter-2 (SGLT2) inhibitors or Glucagon like peptide-1 (GLP1) agonists are safe and effective therapeutic options

Key Words

Glucagon Like Peptide-1 Agonists | SGLT-2 Inhibitors | Diabetes Mellitus

Introduction

Type 2 diabetes mellitus (T2DM) affects over 29 million people, or one out of every 11, in the United States (US).¹ While this is a common condition, T2DM is also associated with significant morbidity and mortality. The risk of mortality is 50% higher for adults with T2DM compared to those without, and is recognized as the 7th leading cause of death in the US.¹ Risks of myocardial infarction (MI) and stroke are increased by 1.8 fold and 1.5 fold respectively, and T2DM is the leading cause of kidney failure, non-traumatic lower limb amputations and new cases of blindness among US adults.¹ Over 25 pharmacologic agents from 9 classes have been approved by the US Food and Drug Administration (FDA) for the treatment of T2DM. All of these have been shown to improve surrogate markers of glycemic control including reducing hemoglobin A1c, and fasting and post-prandial blood glucose. However, the majority of phase III trials for these medications have been of relatively short duration and have not assessed patient-oriented outcomes such as

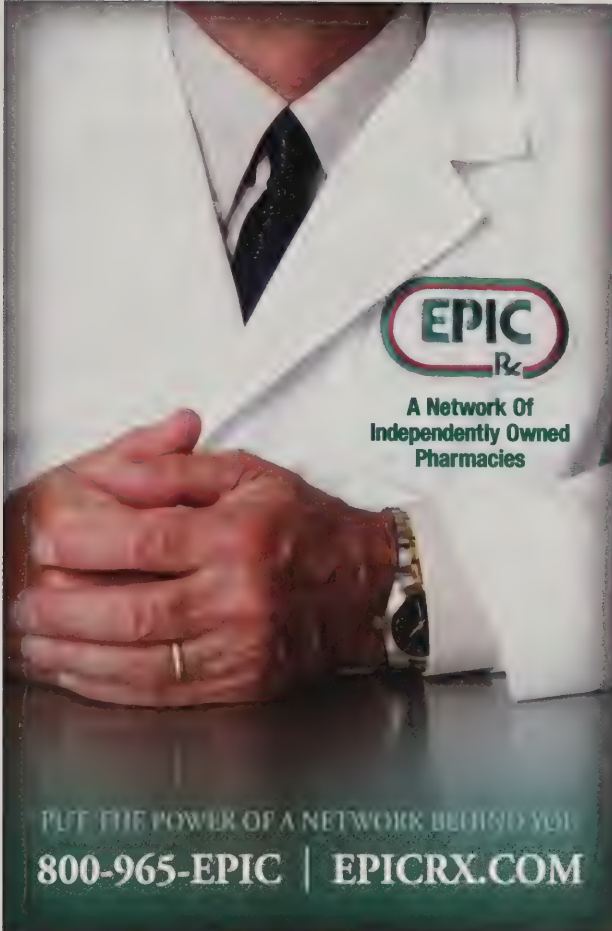
reduction in morbidity or mortality measures.

Multiple guidelines exist to support clinicians treating patients with T2DM. *The Standards of Care in Diabetes* from the American Diabetes Association (ADA) and the *Consensus Statement on the Comprehensive Type 2 Diabetes Management Algorithm* from the American Association of Clinical Endocrinologists/American College of Endocrinology (AAACE/ACE) are most commonly cited.^{2,3} Both guidelines emphasize the cardiovascular benefits of intensive glycemic control based on the results of the original United Kingdom Prospective Diabetes Study (UKPDS) trial and 10-year observational follow-up. The follow-up study showed significant reduction in the risk of all-cause mortality and MI in patients initially randomized to receive intensive therapy with sulfonylureas or insulin, with a larger reduction in risk for patients receiving intensive therapy with metformin.⁴

Other early studies have also shown potential risks of intensive glycemic control in older patients

with longer duration of T2DM and multiple cardiovascular risk factors. The intensive glycemic control arm of the ACCORD trial was stopped early due to findings of increased mortality.⁵ In contrast the ADVANCE and VADT trials showed no difference in cardiovascular or all-cause mortality between treatment groups,^{6,7} and a 10-year follow-up from the VADT trial shows a decrease in major cardiovascular events in patients randomized to intensive therapy.⁸ The findings of these trials emphasize the risks of severe hypoglycemia and its association with mortality, particularly in patients with multiple cardiovascular risk factors.

In 2007, a meta-analysis of 42 clinical trials concluded that use of rosiglitazone, a thiazolidinedione (TZD), was associated with a significantly increased risk of MI and a trend toward increased risk of cardiovascular mortality.⁹ A similar meta-analysis of 19 clinical trials using pioglitazone did not demonstrate this increased risk, instead finding a decreased risk of all-cause mortality, MI or stroke.¹⁰ While these findings indicated that increased cardiovascular risk



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was not a class effect with TZDs, it highlighted the need for long-term cardiovascular data with anti-diabetic agents.

The following year, the FDA released a guidance statement recommending that sponsors of all new anti-diabetic therapies should demonstrate there is not an “unacceptable increase in cardiovascular risk.”¹¹ Within the last 5 years data has emerged to support the impact of certain anti-diabetic agents on all-cause mortality, cardiovascular mortality and composite cardiovascular outcomes. This article will review key trials on the cardiovascular impact of specific anti-diabetic therapies since this guidance was issued [Table 1].

Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Sodium glucose cotransporter-2 (SGLT2) inhibitors are the newest class of agents approved for

treatment of T2DM. SGLT2 regulates glucose reabsorption in proximal renal tubules. SGLT2 inhibitors reduce blood glucose levels by increasing urinary glucose excretion. FDA approved SGLT2 inhibitors include: canagliflozin (Invokana, 2013, Janssen Pharmaceuticals), dapagliflozin (Farxiga, 2014, AstraZeneca Pharmaceuticals) and empagliflozin (Jardiance, 2014, Boehringer Ingelheim Pharmaceuticals). Given the relation between the mechanism of action and renal function, all three agents in this class are contraindicated in patients with severe renal impairment (eGFR <45 ml/min/1.73 m² for canagliflozin and empagliflozin, eGFR <60 ml/min/1.73 m² for dapagliflozin), end-stage renal disease or on dialysis. Other class related precautions include hypotension, acute kidney injury or renal function impairment, urinary tract infections and genital mycotic infections.

The EMPA-REG Outcome study was a large, placebo-controlled prospective study investigating the effect of empagliflozin on cardiovascular morbidity and mortality as add-on therapy in patients with T2DM and high cardiovascular risk.¹² Patients (N=7,020) were randomized to receive empagliflozin 10 mg, 25 mg or placebo for a median of 2.6 years. Background medication regimens related to diabetes or other cardiovascular co-morbidities were not dictated by the study investigators. The majority of patients were treated with recommended agents to reduce cardiovascular risk including angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), statins and aspirin. To be eligible for the study, participants had to be adults with uncontrolled T2DM, a BMI < 45 kg/m², eGFR > 30 ml/min/1.73 m², stable on current diabetic regimen

(or no medications), and have a high risk of cardiovascular events. A high-risk of cardiovascular events was defined by at least one of the following: (1) history of MI, (2) history or stroke, (3) coronary artery disease (CAD) based on imaging or prior revascularization, (4) unstable angina, or (5) occlusive peripheral artery disease (PAD). The enrolled study population had an average age of 63 years, 72% were male and 72% were white. More than half of participants had a T2DM for longer than 10 years and the average A1c was 8%. Background anti-diabetic therapies included metformin (74%), insulin (49%), and sulfonylureas (42%).

The primary outcome, a composite of cardiovascular mortality, MI and stroke, occurred in 10.5% of participants in the empagliflozin group and 12.1% of participants in the placebo group, indicating superiority for empagliflozin (hazard ratio [HR] 0.86, $p=0.04$). Secondary analyses also showed lower risks of all-cause mortality, cardiovascular mortality, and heart failure (HF) hospitalizations in the groups treated with empagliflozin. There were no differences in the rates of MIs or strokes. As the largest risk reductions were seen with HF hospitalizations, it has been suggested this may be the driving force for the observed overall cardiovascular risk reductions.³ Higher rates of genital infections and urosepsis, a rare finding, were found in the empagliflozin group. Other adverse events were similar to placebo. There were no significant differences between doses related to cardiovascular outcomes. The authors caution that this study population included patients at a high risk of cardiovascular events and should not be extrapolated to the general population of patients with T2DM.

Continued on page 25

Patient Case

BL is a 67 yo Caucasian male with a 8 year history of T2DM. He currently takes metformin 1,000 mg po BID, but his A1c remains elevated, most recently 7.8% 2 weeks ago. He has received education on diet and exercise interventions to improve his diabetes control, and has cut out sodas and ice cream from his diet, but has difficulty adhering to all of the recommended changes. He also states that pain in his legs limits his ability to exercise. He recently saw a vascular specialist who took blood pressures in his ankles and his arms and found the ankle-brachial index (ABI) to be 0.84. Other past medical history includes hypertension and GERD.

Questions

- 1. For which of the following trials would BL meet enrollment criteria?**
 - a. EMPA-REG outcome study
 - b. ELIXA study
 - c. EXAMINE study
 - d. LEADER study
- 2. BL differs from the average participant in this study in what way?**
 - a. Most participants were younger
 - b. Most participants were African American
 - c. Most participants were not on metformin
 - d. Most participants had a longer duration of diabetes
- 3. You recommend that BL be started on liraglutide. Based on the findings from the LEADER study what impact might this have?**
 - a. Decreased all-cause mortality
 - b. Decreased cardiovascular mortality
 - c. Decreased rate of MI
 - d. Decreased rate of stroke
- 4. BL should be educated on which of the following potential adverse effects of liraglutide?**
 - a. Gastrointestinal upset
 - b. Hypotension
 - c. Urinary tract infections
 - d. Weight gain

Answers on page 28

TABLE 1:
Comparison of Key Eligibility Criteria and Outcomes of Antidiabetic Cardiovascular Studies

Study	Medication (N)	Eligibility Criteria	Primary Outcome	Secondary CV Outcomes	Key Safety Findings
EMPA-REG Outcome ¹²	Empagliflozin (N=7,020)	Adults with high risk of CV events	Composite: CV mortality, MI and Stroke 10.5% empagliflozin, 12.1% placebo HR 0.86, p=0.04	Favoring treatment: - All-cause mortality - CV mortality - HF hospitalizations No difference between groups: - MI - Stroke - Revascularization	Increased risk of: - Genital infections - Urosepsis
CANVAS ¹³	Canagliflozin (N=10,142)	Age > 30 with CV disease or Age > 50 with > 2 CV risk factors	Composite: CV mortality, MI and Stroke 26.9/1,000 patient-years canagliflozin, 31.5/1,000 patient-years placebo, HR 0.86, p=0.0158	Favoring treatment: - HF hospitalization No difference between groups: - All-cause mortality - CV Mortality - MI - Stroke	Decreased risk of: - Progression of albuminuria - Composite: 40% reduction in eGFR, need for renal-replacement therapy, and death from renal causes - Serious adverse effects Increased risk of: - Amputations - Fractures Volume depletion - Genital infections - Diuresis
LEADER ¹⁵	Liraglutide (N=9,340)	Age > 50 with CV comorbidity or Age > 60 with 1 CV risk factor	Composite: CV mortality, MI and Stroke 13% liraglutide, 14.9% placebo, HR 0.87, p=0.01	Favoring treatment: - All-cause mortality - CV mortality No difference between groups: - MI - Stroke - HF Hospitalizations - Revascularization	Decreased risk of: - Nephropathy - Severe hypoglycemia Increased risk of: - GI adverse events - Discontinuation due to adverse events
ELIXA ¹⁶	Lixisenatide (N=6,068)	Acute coronary event within prior 180 days	Composite CV mortality, MI, Stroke, hospitalization for unstable angina 13.4% Lixisenatide, 13.2% placebo, HR 1.02, p=0.81	Favoring treatment: - None No difference between groups: - CV Mortality - MI - Stroke - All-cause mortality - Unstable angina hospitalizations - HF hospitalizations - Revascularization	Increased risk of: - Discontinuation due to adverse events - Nausea or vomiting
SUSTAIN-6 ¹⁷	Semaglutide (N=3,297)	Age > 50 with CV comorbidity or Age > 60 with 1 CV risk factor	Composite CV mortality, MI, stroke 6.6% semaglutide, 8.9% placebo, HR 0.74, p=0.02	Favoring treatment: - Stroke - Revascularization No difference between groups: - All-cause mortality - CV Mortality - MI - Stroke	Decreased risk of: - Nephropathy - Serious adverse events Increased risk of: - Diabetic retinopathy - Discontinuation due to adverse events - Gastrointestinal disorders

Table 1 continued on page 24

TABLE 1 *continued*
Comparison of Key Eligibility Criteria and Outcomes of Antidiabetic Cardiovascular Studies

Study	Medication (N)	Eligibility Criteria	Primary Outcome	Secondary CV Outcomes	Key Safety Finding
TECOS ¹⁸	Sitagliptin (N=14,671)	Age > 50 with CV disease	Composite CV mortality, MI, stroke, hospitalization for unstable angina 11.4% sitagliptin, 11.6% placebo, HR 0.98, p=0.65	Favoring Treatment • None No difference between groups: • All-cause mortality • HF hospitalizations • MI • Stroke	No significant differences in adverse events
SAVOR-TIM ¹⁹	Saxagliptin (N=16,492)	Age > 40 and CV event or Age > 55 (men) or 60 (women) with CV risk factor	Composite CV mortality, MI, Stroke 7.3% saxagliptin, 7.2% placebo, HR 1.00, p=0.99	Favoring Placebo: • HF hospitalizations (3.5% saxagliptin, 2.8% placebo, HR 1.27, p=0.007) Favoring Treatment • None No difference between groups: • All-cause mortality • CV mortality • MI • Stroke • Revascularization	Increased risk of: • Minor hypoglycemia
EXAMINE ²⁰	Alogliptin (N=5,380)	Acute CV event within prior 15–90 days	Composite CV mortality, MI, Stroke 11.3% alogliptin, 11.8% placebo, HR 0.96, p=0.32	Favoring Treatment • None No difference between groups: • All-cause mortality • CV mortality • MI • Stroke • HF hospitalizations	No significant differences in adverse events

CV=Cardiovascular; HF=Heart Failure; HR=Hazard Ratio; MI=Myocardial Infarction

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Directions for taking this issue's quiz:

This issue's quiz on **Recent Updates on the Cardiovascular Risks and Benefits of Antidiabetic Agents** can be found online at www.PharmCon.com.

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The CANVAS study, published in June 2017, enrolled patients (N=10,142) with uncontrolled T2DM and either age > 30 years and history of cardiovascular disease or age > 50 years and multiple cardiovascular risk factors.¹³ In this study a history of cardiovascular disease was defined as prior stroke, MI, hospitalization for unstable angina, coronary revascularization including coronary artery bypass graft or percutaneous coronary intervention, and PAD including revascularization, symptomatic disease or amputation. Cardiovascular risk factors included: (1) duration of diabetes > 10 years, systolic blood pressure >140 mmHg on > 1 antihypertensive agent, current smoking, albuminuria, or HDL < 38.7 mg/dL. The average age of participants was 63 years, 65% were male and 78% were white. The average A1c at enrollment was 8.2% and the average duration of diabetes was 13.5 years. Participants received canagliflozin 300 mg, 100 mg or placebo as add-on antidiabetic therapy and were followed for a median of 2.5 years. Results were reported as events per 1,000 patient-years, and not percentages as in the other studies discussed in this review. Less patients in the combined canagliflozin groups experienced the primary composite endpoint of cardiovascular mortality, MI or stroke (27 vs. 31 per 1,000 patient-years, HR 0.86, p=0.0158), though the individual components of the composite outcome were not found to be statistically significantly different from placebo. All-cause mortality rates were not different between groups, though the risk of HF hospitalizations was lower in the canagliflozin group. While patients with eGFR <30 ml/min/1.73 m² were excluded from the CANVAS study, progression of albuminuria occurred less frequently in the canagliflozin group than placebo. In addition to increased rates of volume depletion, urinary and genital infections, this study also found increased rates of fractures and amputations in the canagliflozin group.

Macrovascular outcomes were not included in the initial prescribing information for any of these agents, though the package insert for empagliflozin was updated in December 2016 to reflect the results of the EMPA-REG Outcomes study. Empagliflozin currently carries an indication "to reduce the risk of cardiovascular death in adult patients with T2DM and established cardiovascular disease."¹⁴ Changes to package labeling have not yet been approved for canagliflozin based on the recently published CANVAS study. The package labeling for canagliflozin and dapagliflozin include a statement that there are no clinical studies establishing evidence of macrovascular risk reduction. There are also multiple ongoing studies with empagliflozin including the DECLARE-TIMI 58 trial, which will help determine if the cardiovascular benefits shown with empagliflozin and canagliflozin apply to the SGLT2 drug class.

Glucagon-like Peptide 1 (GLP1) Agonists

Glucagon-like peptide 1 (GLP1) is an incretin mimetic hormone with a multitude of physiologic actions, including triggering insulin release and inhibiting glucagon secretion in response to blood glucose levels. GLP1 agonists are synthetic analogs that activate GLP1 receptors, but have longer half-lives by avoiding natural degradation enzymes. Currently approved products include: exenatide (Byetta, 2005 and Bydureon, 2012, AstraZeneca Pharmaceuticals), liraglutide (Victoza, 2010, Novo Nordisk), albiglutide (Tanzeum, 2014, GlaxoSmithKline), dulaglutide (Trulicity, 2014, Eli Lilly and Company), and lixisenatide (Adlyxin, 2016, Sanofi-Aventis). Products vary in regards to injection device, half-life, and dosing frequency. Of note, liraglutide is also FDA approved under a different brand name (Saxenda) and at a higher dose for chronic weight management in patients with a BMI > 30 kg/m² or BMI > 27 kg/m² with a weight-

related comorbid condition, including diabetes. Combination products that include long-acting insulin and a GLP1 agonist are also approved, including insulin degludec/liraglutide (Xultophy, 2016, NovoNordisk) and insulin glargine/lixisenatide (Soliqua, 2016, Sanofi-Aventis). Package labeling for exenatide and lixisenatide only list hypersensitivity as contraindications, while other agents in this class are also contraindicated in patients with a personal or family history of medullary thyroid carcinoma or personal history of multiple endocrine neoplasia syndrome based on findings of animal studies and post-marketing reports. Precautions include risk of pancreatitis and acute kidney injury, and risk of hypoglycemia when used in combination with other agents like insulin. Recommendations suggest avoiding use in patients with severe gastrointestinal disease.

Liraglutide

The LEADER Trial prospectively investigated the impact of liraglutide on cardiovascular outcomes.¹⁵ Participants with uncontrolled T2DM were eligible if they were age > 50 years with one cardiovascular comorbidity, or age > 60 years with one cardiovascular risk factor. Cardiovascular comorbidities included: CAD, stroke, PAD, > stage 3 chronic kidney disease (CKD), or New York Heart Association HF class II or III. Cardiovascular risk factors included microalbuminuria, proteinuria, hypertension with left ventricular hypertrophy, left ventricular systolic or diastolic dysfunction, or PAD. Exclusions to enrollment included type 1 diabetes, use of GLP1 agonists, dipeptidyl peptidase 4 (DPP4) inhibitors, pramlintide, or rapid-acting insulin, family or personal history of multiple endocrine neoplasia type 2 or medullary thyroid cancer, or MI or stroke within 14 days of randomization. Patients (N=9,340) were randomized to receive 1.8 mg of liraglutide or placebo and continued on treatment for a

median of 3.5 years. The average age of the study population was 64 years, with 64% male, average duration of diabetes of 13 years, and average A1c at enrollment of 8.7%. Background diabetes medications included metformin (76%), sulfonylureas (50%), and insulin (44%).

The primary outcome, a composite of cardiovascular mortality, MI, or stroke, occurred in 13% of the liraglutide group compared to 14.9% of the placebo group (hazard ratio 0.87, $p=0.01$). Cardiovascular and all-cause mortality rates were also statistically significantly lower in the liraglutide group, as were rates of nephropathy events. No statistical differences were seen in the rate of MI or stroke. In subgroup analyses benefits were found to be greater in patients with impaired renal function (eGFR <60 ml/min/1.73 m²) and established cardiovascular disease at baseline. Gastrointestinal adverse events, including those that lead to discontinuation of therapy, were increased in the liraglutide group.

Lixisenatide

The effect of lixisenatide in patients (N=6,068) with T2DM and MI or hospitalization for unstable angina in the preceding 180 days followed for a median of 25 months was evaluated in the ELIXA Trial.¹⁶ Enrolled patients had an average age of 60 years, were predominately male (70%) and white (75%). Average A1c was 7.6% and average duration of diabetes was 9 years. A majority of patients had hypertension (76%) and prior percutaneous coronary intervention (67%) at baseline. The majority of qualifying events were MIs, occurring an average of 72 days prior to randomization. Glycemic management including initiation, discontinuation and dose adjustment of other glucose lowering agents aside from GLP1 agonists and DPP4 inhibitors was

at the discretion of the treating physician. There was no difference between lixisenatide and placebo groups in the primary outcome, a composite of cardiovascular mortality, MI, stroke, or hospitalization for unstable angina. There were also no differences in secondary outcomes including individual components of the composite outcome, all-cause mortality, HF hospitalizations, or coronary revascularization. Patients in the lixisenatide group had statistically lower A1c values and more weight loss, they also had statistically higher rates of discontinuation due to adverse events driven by nausea and vomiting.

The ELIXA study population differed from trials previously discussed in this review because it included patients with recent cardiovascular events not just those at increased cardiovascular risk. While it is reassuring that lixisenatide does not negatively impact outcomes in this population, the results of this study does not indicate benefit in the adding lixisenatide to baseline medication regimens for patients with recent cardiovascular events.

Semaglutide

A new drug application for Semaglutide, a once-weekly GLP-1 agonist, was submitted to the FDA by Novo Nordisk in December 2016, but is not yet approved. Patients (N=3,297) with uncontrolled T2DM on <2 oral antidiabetic agents, with or without basal or premixed insulin, were enrolled in the 2-year SUSTAIN-6 trial to assess the cardiovascular effects of this investigational drug following the same inclusion criteria as the LEADER trial.¹⁷ Exclusion criteria included use of GLP1 agonists, DPP4 inhibitors, or basal insulin, coronary or cerebrovascular event within 90 days prior to enrollment, planned revascularization and dialysis. The

average age of enrolled patients was 65 years, 60% were male, average A1c was 8.7% with a 14 year average duration of diabetes.

The primary composite outcome of cardiovascular mortality, MI and stroke occurred less often in patients in the semaglutide group (6.6%) than in the placebo group (8.9%, HR 0.74, $p=0.02$), though stroke was the only component that had a significant difference individually (1.6% vs. 2.7%, HR 0.61, $p=0.04$). More patients in the semaglutide group developed diabetic retinopathy (3.0% vs. 1.8%, HR 1.76, $p=0.02$), while fewer patients developed new or worsening nephropathy (3.8% vs. 6.1%, HR 0.64, $p=0.005$) and revascularization (5% vs. 7.6%, HR 0.65, $p=0.003$) in the semaglutide group.

Similar to the lixisenatide study, this trial demonstrates the cardiovascular safety of semaglutide, while falling short of demonstrating the mortality benefit shown with liraglutide. The benefits in terms of risk reduction of nonfatal stroke, revascularization and nephropathy progression may have clinical implications, but should be evaluated in concert with the lack of impact on all-cause or cardiovascular mortality. Studies investigating the impact of exenatide (EXSCEL) and dulaglutide (REWIND) on composite outcomes of cardiovascular mortality, MI and stroke in patients with diabetes and history of cardiovascular disease are currently ongoing.

Dipeptidyl Peptidase 4 (DPP4) Inhibitors

DPP4 is the enzyme responsible for degradation of naturally occurring GLP1. DPP4 inhibitors including sitagliptin (Januvia, 2006, Merck & Co), saxagliptin (Onglyza, 2009, AstraZeneca), linagliptin (Tradjenta, 2011, Boehringer Ingelheim Pharmaceuticals), and alogliptin (Nesina, 2013, Takeda Pharmaceuticals), slow this

degradation allowing endogenous GLP1 to exert its endocrine actions longer. Recent studies have shown that use of DPP4 inhibitors neither increases nor decreases rates of cardiovascular outcomes. In the TECOS study, sitagliptin was found to be non-inferior to placebo after three years of follow-up for the composite endpoint of cardiovascular mortality, MI, stroke or hospitalization for unstable angina in patients with T2DM and existing cardiovascular disease, defined as history of CAD, stroke, or PAD.¹⁸ In addition, no differences were found between groups for secondary outcomes including HF hospitalizations or all-cause mortality. The SAVOR-TIMI trial similarly found no difference in composite endpoint of cardiovascular mortality, MI and stroke when patients with T2DM and established CAD or multiple risk factors were randomized to receive saxagliptin or placebo as add-on therapy with two years of follow-up.¹⁹ However, this trial did find an increased risk of HF hospitalizations in the treatment group (3.2% vs. 2.8%, HF 1.27, $p=0.007$). Similar to the ELIXA trial, the EXAMINE trial enrolled patients with uncontrolled T2DM and a recent coronary event (15-90 days prior to enrollment).²⁰ Add-on treatment with alogliptin was non-inferior to placebo regarding primary composite outcome of cardiovascular mortality, MI and stroke and secondary outcomes including HF hospitalizations with a follow-up of 1.5 years.¹⁰

These findings indicate that treatment with DPP4 inhibitors is likely safe in patients with cardiovascular disease, but is unlikely to confer benefits aside from glycemic control. The ongoing CAROLINA trial will evaluate the effect of linagliptin compared to glimepiride on cardiovascular outcomes in patients at high-risk. The findings of increased HF hospitalizations in the SAVOR-TIMI trial calls for greater scrutiny of this class, though these findings have not been confirmed in additional trials. At this time, it

is prudent to avoid saxagliptin and to consider use of anti-diabetic agents other than DPP4 inhibitors in patients with HF or at high risk, though further studies to evaluate this risk are needed.

Conclusions

Data on the cardiovascular effects of anti-diabetic agents has begun to emerge since the FDA guidance document was published in 2008. To date evidence relates only to specific agents. Consistent results within drug classes have not been demonstrated. While all patients with T2DM are thought to be at increased risk for MIs and strokes, these studies have focused on patients with additional cardiovascular risk. This is in contrast to the evidence for all-cause mortality reduction with metformin from the UKPDS trial, which enrolled patients with uncontrolled T2DM regardless of additional cardiovascular risk factors. Inconsistent definitions of increased cardiovascular risk have been used among the studies, with some focusing on age and risk factors and others focusing on recent events. This limits comparison of results.

The 2017 update of the ADA *Standards of Care* added a recommendation to consider empagliflozin or liraglutide in patients with established cardiovascular disease.² The AACE/ACE guidelines 2017 update include discussion of the cardiovascular benefit demonstrated by empagliflozin, but do not specifically comment on findings related to liraglutide.³ Both guidelines also emphasize the need to control non-glycemic cardiovascular risk factors including weight, blood pressure, lipid management including statin therapy, and aspirin therapy to improve overall outcomes and reduce atherosclerotic cardiovascular risk.

Pharmacists will need to stay abreast of this evolving field of data. There are currently multiple ongoing studies that may help

provide insights into whether the cardiovascular effects, both beneficial and harmful, are specific to individual drug products or have wider applicability to drug classes.

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ANSWERS

1. Answer: D

The EXAMINE and ELIXA studies included patient with recent cardiovascular events (15-90 days for EXAMINE and <180 days for ELIXA). BL has not had a coronary event [Answers B and C are incorrect]. While BL's ABI <0.9 and symptoms indicated diagnosis of peripheral arterial disease (PAD), EMPA-REG only included patients with occlusive PAD, and BL does not have evidence of occlusion [Answer A incorrect]. ABI <0.9 is considered a cardiovascular risk factor qualifying patients over the age of 60 for inclusion in the LEADER study [Answer D is correct].

2. Answer: D

The average age of participants in the LEADER study was 64 years, which is very similar or

slightly younger than BL's age [Answer A incorrect]. Participant race was not reported in the LEADER study, including the supplementary material [Answer B incorrect]. 76% of participants were on metformin at the time of enrollment [Answer C incorrect]. The mean duration of diabetes was 13 years, which is longer than BL's duration of diabetes [Answer D correct].

3. Answer: A and B

The primary endpoint of the LEADER study was a composite of cardiovascular mortality, MI and stroke. The rate of this composite was lower in the liraglutide group than the placebo group. Secondary analyses showed that the independent components of MI rates and stroke rates were not different between group [Answers C and D incorrect],

while all-cause mortality and cardiovascular mortality were significantly lower in the treatment group [Answer A and B correct]

4. Answer: A

Liraglutide is a GLP1 agonist. GLP1 agonists typically lead to weight loss, not weight gain [Answer D incorrect]. Hypotension and urinary tract infections are side effects of SGLT2 inhibitors [Answers B and C incorrect]. The most common adverse effects of GLP1 agonists are gastrointestinal upset, specifically nausea and vomiting. This was confirmed with findings from the recent cardiovascular trials which showed increased rates of this side effect, including intolerances that led to treatment discontinuation. [Answer A correct]. ●

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Legislative and Policy Updates

Changes in Opioid Prescribing in Maryland — Effective July 1

A new opioid prescribing policy took effect July 1, 2017 for both Medicaid Fee-for-Service and all eight Managed Care Organizations (MCOs). Of particular interest to pharmacists: Prior authorization will be required for long-acting opioids, fentanyl products, methadone for pain and any opioid prescription that results in a patient exceeding 90 morphine milliequivalents (MME) per day. A standard 30-day quantity limit for all opioids will be set at or below 90 MME per day. The prior authorization must be obtained every 6 months. There are requirements to successfully achieve the prior authorization. Patients with cancer, sickle cell anemia or those in hospice will be excluded from the prior authorization, but are to be kept at the lowest effective dose of opioids for the shortest period of time. HealthChoice MCOs may implement additional requirements or limitations.

Maryland Department of Health is making tweaks to the provision based on feedback from the pharmacy community.

Pharmacist Registration in Maryland Prescription Drug Monitoring Program — Deadline July 1

As the *Maryland Pharmacist* went to print, just over 56 percent of pharmacists had registered in the PDMP. Please ensure you register. For more information visit www.marylandpharmacist.org — Hot Topics — PDMP Registration.

NCPA Congressional Fly-in

MPhA staff and members participated in NCPA's 2017 Congressional Fly-in in April. A team of engaged MPhA members held meetings with nine out of the 10 offices of the Maryland Congressional Delegation. Participants met with Members of Congress and staff to solicit support for legislation focused on any willing pharmacy, provider status, DIR fees among other topics.



(L-R) George Garmer, Sherrie Sims, Rep. Anthony Brown (D-MD-4), Aliyah Horton



(L-R) Matthew Balish, Horton, Rep. Andy Harris (R-MD-1), Sims, Garmer

Maryland delegation participants not pictured: Brian Hose and Larry O'Connor

We Work for Health Coalition Congressional Visits

MPhA has long been a partner of the We Work for Health Coalition. MPhA Executive Director Aliyah Horton partnered with Gene Ransom, executive director of MedChi and Martin Rosendale member of the Maryland Technology Council's Executive Team in meetings with the staff of Senators Ben Cardin and Chris Van Hollen to discuss support for the passage of a

clean reauthorization of PDUFA (Prescription Drug User Fee Act) and to express our concerns about legislation introduced to allow foreign drug importation as a way to reduce medication costs.



Gene Ransom, Sen. Ben Cardin Staff, Martin Rosendale, Aliyah Horton

Summer Meetings for Pharmacist Prescribing Contraceptives Regulations

The stakeholders are working through the summer to provide input to the Board of Pharmacy on SB 363/HB613 Pharmacists-Contraceptives Prescribing. Stakeholders engaged in the process include: MPhA, as well as the Maryland Chapter of the American College of Obstetricians and Gynecologists; Maryland Chapter of the American Academy of Pediatrics; Maryland Affiliate of the American College of Nurse-Midwives; Planned Parenthood of Maryland; Maryland Nurses Association; Maryland Association of Chain Drug Stores; University of Maryland School of Pharmacy, University of Maryland Eastern Shore School of Pharmacy; Notre Dame of Maryland University School of Pharmacy; and Nurse Practitioner Association of Maryland. The Boards of Physicians and Nurses must be consulted during the process. The regulations must be promulgated by September 2018, for implementation in January 2019. ●

Executive Director's Message

Thank you to the many volunteers who supported MPhA's 135th Annual Convention, "Taking Pharmacy to New Heights!" Your collective efforts served to support an informative and relaxing Annual Convention. Our foray in to Western Maryland yielded smaller attendance than past conventions, but reaped great rewards in that content was shared that had immediate implications for pharmacy practice; new friendships were forged; and seeds of innovation were planted. Tough questions were asked related to the pharmacist's role in addressing the opioid epidemic; diversity in drug trials; how to positively affect patients receiving outpatient chemotherapy; and general safety in the pharmacy.

Thank you to the board members who cycled off the board this year: Hoai-An Truong, Ashley Moody, Larry Hogue and Mark Ey. Your contributions as trustees challenged and inspired your board colleagues and me. I look forward to working with you in different capacities to advance the mission of MPhA.

I salute our 2017 award winners who received well-deserved recognitions. I know they will continue to be leaders, mentors, advocates and innovators who serve the pharmacy community. As we take the summer to plan for 2018, we will need the time and talents of our many award winners and YOU to meet our organizational charge. President Cherokee Layson-Wolf has challenged MPhA to facilitate the pharmacy community in Maryland to be "provider ready."

What does being provider ready mean to you and your practice setting? How can MPhA help you be provider ready? Please visit www.marylandpharmacist.org and click on the "Provider Ready" survey to share your thoughts and ideas.

We have made some tweaks to our website. We've added a "Hot Topics" tab to direct you to information and guidance on the opioid issues, expedited partner therapy, collaborative practice, emergency preparedness and other topics, where you may need information



and guidance. The "Resources" tab has been restructured to direct you to information tailored for the Pharmacist, Pharmacy Intern/ Technician and your Business, etc. Let us know what you think and if there are other areas that need to be addressed. MPhA's activities are only meaningful if they are relevant to you.

Enjoy the rest of your summer, ●

A handwritten signature in dark ink, appearing to read "Aliyah N. Horton".

Aliyah N. Horton, CAE
Executive Director



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CARETM is redefining pharmacy through forward-thinking, comprehensive programs and services, coupled with its unique forward-thinking sourcing strategies. A mission based organization, CARE Pharmacies, is keenly focused on delivering value to its customers, business partners, and shareholders. CARE members enjoy access to direct manufacturer contracts, specialty hub services, and access to limited distribution products and networks.

The corporate team at CARETM works to represent the interests of its members, support their growth, promote their profitability, and enable them to provide superior patient satisfaction and outcomes. CARETM offers a full range of purchasing solutions, managed care services, and compliance programs designed to meet the dynamic needs of the independent community pharmacist.

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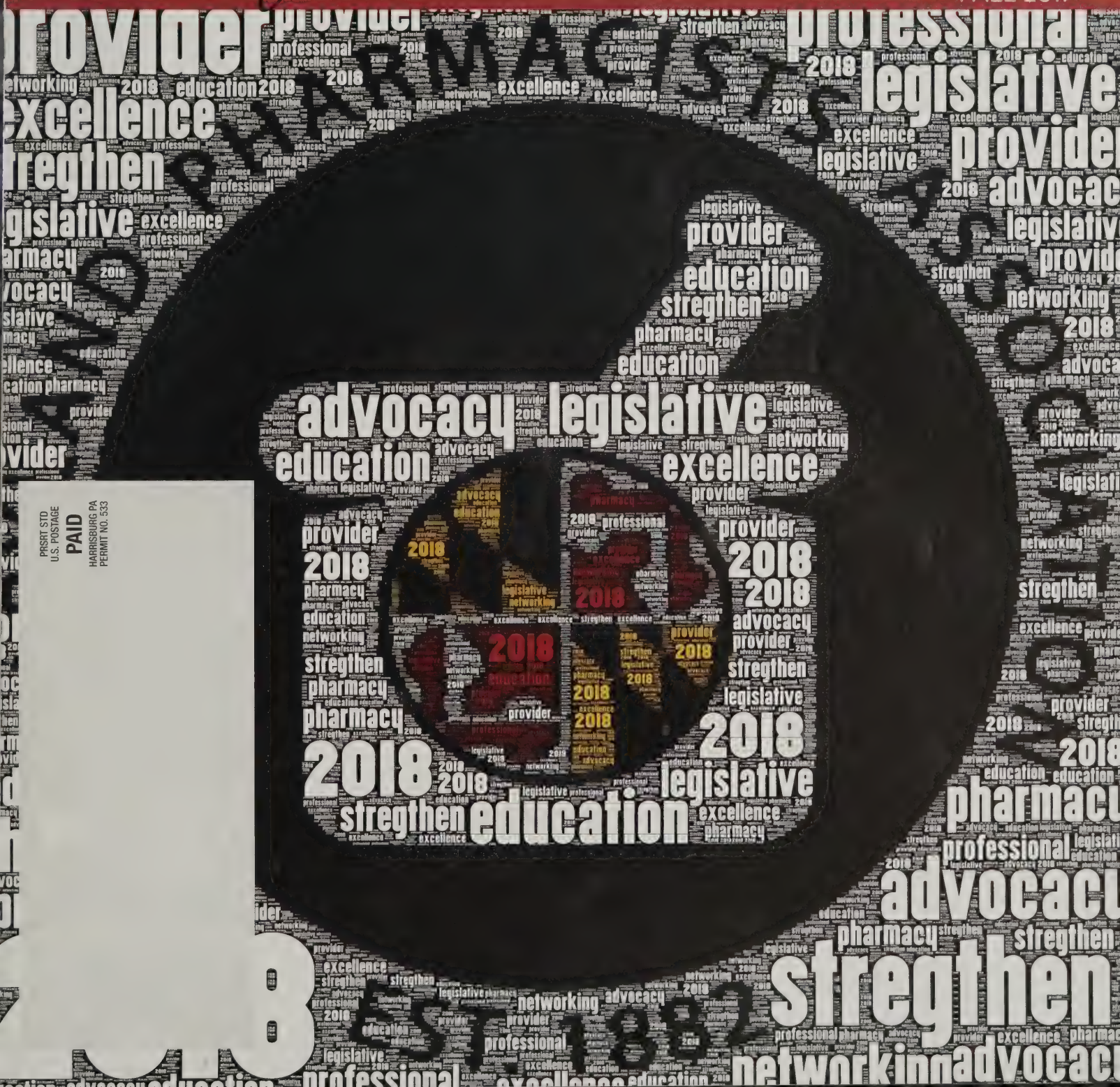
The latest on provider status at the federal, state levels

Lack of provider status for pharmacists is barrier to pain relief for patients

Mineralocorticoid Receptor Antagonists: The Wonder Class

Maryland Pharmacist

FALL 2017



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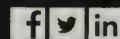
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Renew Today! Membership Matters

We are look forward to working with you to have a proactive and productive 2018!



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American Pharmacists Month

YOUR PHARMACIST

KNOW

YOUR MEDICINE



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Special thanks to GraphTech,
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President's Pad



Dear Fellow MPhA Members:

Happy Fall! The last time we saw each other we were just getting back from the annual meeting, so I'm excited for what this upcoming fall season brings. Becoming "Provider Ready" will certainly be a journey. We will learn much along the way and will experience both success and challenges, and MPhA will be with you at every step.

In preparation for our year, the Board of Trustees and committee chairs met at MPhA headquarters for orientation and to identify priorities to focus on this year, particularly activities that focus on helping our members

become "Provider Ready," and identifying other activities that provide value to our members. We've come up with some great ideas, and I am confident that our Board of Trustees, Executive Board and committees are excited to work together this year to bring our membership various activities to learn and network.

We have already started this season with various educational sessions including expedited partner therapy and collaborative practice agreements, and in October we have planned an immunizations session for technicians and a session on FDA resources to improve medication safety. There has also been collaborative work on the contraceptive prescribing regulations involving various stakeholders.

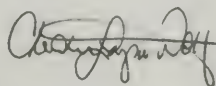
Please take a look at our calendar of events on the marylandpharmacist.org website and read the Monday Message. We look forward to having our members join us at all these upcoming events, and you're also welcome to also join us at our monthly meetings. I hope you've noticed the increased presence and messaging via the MPhA Facebook page. Under the direction of Aliyah Horton, the MPhA APPE students have worked hard to share info on the page and highlight various activities. We hope you "Like" and share so that others can be aware of all the opportunities MPhA offers. Fall also is our annual membership campaign so I hope you can support MPhA's continued efforts to provide education and advocacy on your behalf by renewing your membership!

As we enter into American Pharmacists Month, I want to give a big THANK YOU to all of you who work every day to serve our patients, share your expertise and support your colleagues. We are a network of pharmacists, technicians, and student pharmacists and through our collective efforts we work to provide our patients' medications safely and effectively, and help solve medication-related problems and provide strategies to improve medication adherence in all the settings that we serve.

- To student pharmacists: You are our future. Your energy and enthusiasm for the profession and for your patients are inspirational.
- To technicians: You are our backbone. Your support is vital to help us serve our patients in the best way possible.
- To pharmacists: Your breadth and depth in how we serve patients is expansive, and your expertise and dedication to pharmacy is a testament to the important role we can play in the health care team.

I wish you all a very happy American Pharmacists Month! ●

Kindest regards,



Cherokee Layson-Wolf
President

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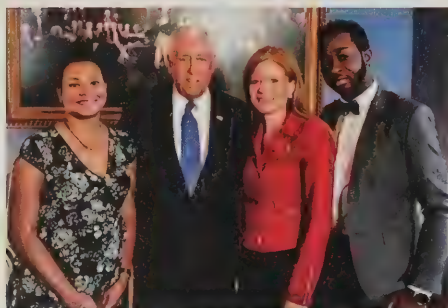
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Member Mentions & News You Can Use



MPhA Advocates for PDUFA Reauthorization and against Importation of Drugs

On July 19, MPhA worked with a coalition of healthcare representatives to encourage members of the Maryland Congressional Delegation to protect pharmacist employees at FDA by supporting passage of the Prescription Drug User Fee Development Act (PDUFA). If PDUFA reauthorization had not passed by a September deadline, mandatory pink slips would have been required to be distributed. We also met with members to raise concerns about the safety and efficacy of legislation introduced that would allow for foreign drug importation.

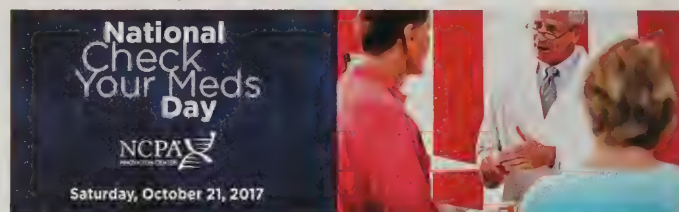
Pharmacist Advocacy in Annapolis

Thank you to Stephen Wiener, Jerry Herpel (past president) and Brian Hose (past president) for their role in educating the Maryland Insurance



Administration and members of the House Health and Government Operations Committee on the impact PBMs have on patient access to medications, specialty drugs, medication pricing and reimbursements to pharmacies. This latest meeting of the pharmaceutical services working group also included representatives from insurance, managed care and PBM stakeholders.

Don't Forget to Prepare Your Pharmacy for National Check Your Meds Day – October 21, 2017

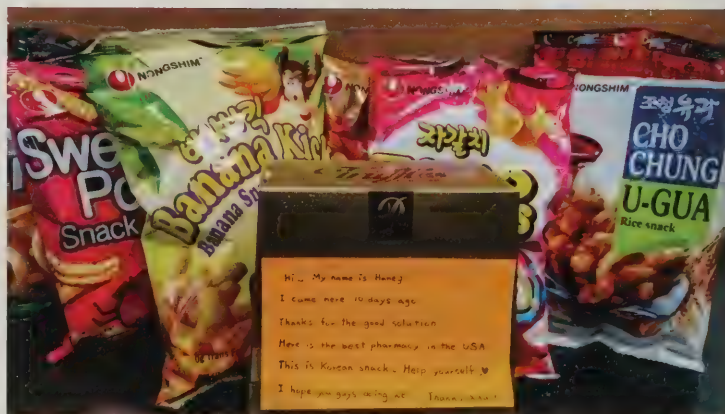


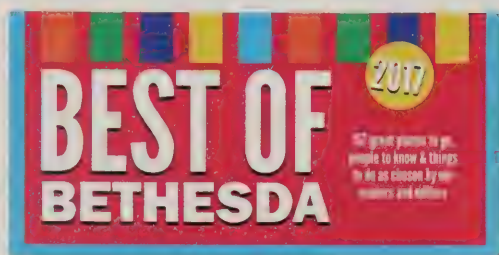
With 90% of the country's population living within five miles of a pharmacy, you're the community's most accessible health care provider. Demonstrate your expertise and value on October 21 for the inaugural National Check Your Meds Day. Sponsored by Consumer Reports and supported by NCPA, patients are encourage to bring their prescription medications and supplements to their local pharmacy for a brown bag medication review. Learn more at ncpanet.org.

Halethorpe Pharmacy – Recognized as "Best in the World"

"You just never know how you are going to touch someone's life. A customer came into one of my pharmacies the other day. English is not her first language. For those of you that don't know, I have traveled all over the world and been in this woman's shoes, figuratively of course. I emphasize to my staff the importance of treating everyone the same. It is an easy sell. The employees I get to work with are truly stellar individuals with gigantic hearts. How many bosses can say that?

In spite of the language barrier my staff went to work, figured out what she needed and took care of her. This is the everyday caring of my awesome staff. Several days after this customer's initial visit she came back to the pharmacy with the gift and note pictured. It is a basket full of snacks from her native Korea. Words cannot describe the joy this kind gesture brought this small business owner and his staff. I am proud of the team we have at Halethorpe Pharmacy and Independent Drug. They make our communities better places." – George D. Garner, RPh





Bradley Care Drugs – Best of Bethesda 2017

Bradley Care Drugs was selected for the 2017 Best of Bethesda Award in the Pharmacies Category. Owner David Posner is a pharmacist and member of MPhA. The pharmacy was recognized as a local that enhances the positive image of small business through service to their customers and community. They are also recognized as making Bethesda a great place to live, work and play. ●

WELCOME NEW MPhA MEMBERS

Andrea Corner
Sara Ann DeVecchio
Patricia Dieso
Mandop M Fonkeng
Jong Yun Han
Ellen Kathleen Herrington

Oluwatoyin Ikujuni
Rodney Lumor
Mia Lynch
Onyinyechi Mgbenka
Raisha Nagar
Kate Naper

Chijioke Onejeme
Katherine Olsen Patel
Christina Robyn Sanborn
Alexa Sanna
Pasang Sherpa
Evelyn Umana

Thank you 2017 Corporate Sponsors



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For more information on being a part of North America's fastest growing drug chains over the past five years, email Mike Wysong, CEO, at mwyson@carepharmacies.com.



MEMBERSHIP MATTERS

RENEW YOUR MEMBERSHIP FOR 2018 TODAY!!

Thank you for your membership in MPhA! You have been a part of the only state-wide professional society representing all practicing pharmacists, pharmacy technicians and student pharmacists in Maryland. We are looking forward to working with you to have a proactive and productive 2018!

If you have not already renewed your membership for 2018, visit www.marylandpharmacist.org, login to your account and click **Renew my Membership**. Please call the office at 443-583-8000 if you have any questions.

- **POLICY AND ADVOCACY** – MPhA is your voice for legislative and regulatory matters. With member input, MPhA collaborates with elected leaders and other pharmacy stakeholders to positively impact pharmacy practice and the public's health. In both Annapolis and Washington, DC, we are working to advance pharmacy scope of practice and eliminate barriers to pharmacists providing care. We need you to weigh in on key issues that impact the profession - provider status, tech check tech, medication administration, opioids, and medication affordability, among other hot topics. Mark your calendar for the annual Maryland Pharmacy Coalition Legislative Day on February 20 in Annapolis, MD.
- **MARYLAND PHARMACY LAW** – MPhA members receive a discount on the purchase price of our Pharmacy Law Book. The 2018 edition is revised to focus on key areas of pharmacy practice and includes a new section to support studying for the MPJE and frequently asked questions. It will be available for purchase in January 2018.
- **CONTINUING EDUCATION** – The MPhA Mid-Year Meeting and Annual Convention offer diverse live continuing education programs that are relevant to all areas of practice. MPhA members receive a reduced registration fee when earning CE credits for their licensure renewal and training on the changes happening in pharmacy practice. The 2018 Mid-Year Meeting is on February 18 in Annapolis, MD. We also host live and web-based CE for pharmacists and pharmacy technicians.
- **COMMUNICATIONS** – MPhA is your resource for the latest news in the pharmacy industry in Maryland through the quarterly journal, *Maryland Pharmacist*, bi-weekly e-newsletter, *Monday Message*, and social media. Follow us on Twitter @MDPharmacist and www.facebook.com/MarylandPharmacistsAssociation.
- **NETWORKING** – MPhA hosts events throughout the year to provide opportunities for our members to network and engage with community stakeholders and others to discuss issues that impact work-life balance, professional development and public health issues. MPhA also hosts myriad committees, with tasks big and small to advance MPhA's mission and provide opportunities to collaborate with other professionals.
- **RESOURCES** – Looking for a job or career resources? MPhA's Career Center has job announcements and resume development tools. MPhA serves as a portal for nominations to serve on the Maryland Board of Pharmacy, and other state commissions and task forces. In addition, there are peer recognition opportunities via MPhA's annual professional practice, community service and innovation awards. ●

MPhA MEMBER SERVICE PARTNERS

MPhA-specific links and additional information on these partners can be found on the MPhA Resources page.

- **Pharmacists Mutual** can provide up to a **30% discount to MPhA members** on disability insurance and offers a complete range of professional, business and personal insurance products and services.
- **Credible Student Loan Consolidation and Refinancing** marketplace offers student loan refinance rates significantly lower than your initial student loan rates, with rates below 2%! **The average user that refinances with Credible saves over \$11,000.**
- **InfiniTrak** is a cost effective and complete solution to all your DSCSA compliance requirements, centralizing and automating all the business requirements and processes required by the law. **MPhA members receive a 25% discount.**
- **Edelman Financial Service** provides MPhA members with a free Financial Plan and free access to any Edelman Financial education seminar (over a \$800 value).

SAVE THE DATE - REGISTRATION OPENS IN NOVEMBER

Another Can't Miss MPhA Mid-year Meeting

MPhA

- Promoting Excellence in Pharmacy Practice
- Strengthening the Profession of Pharmacy
- Advocating for all Maryland Pharmacists



2018 MPhA Mid-year Meeting

Sunday, February 18, 2018

Doubletree by Hilton Hotel Annapolis

210 Holiday Court
Annapolis, MD 21401
410-224-3150

CE Topics:

- Medicinal Cannabis
- Payment for Pharmacist Services
- Contraceptive Prescribing
- Opioid Epidemic
- Tech Check Tech
- Medication Adherence in Psychiatric Patients
- Board of Pharmacy Specialties
- Pharmaceutical Calculations for Technicians

Other Events:

- Awards
- House of Delegates
- Closing Reception

Sleeping Rooms: \$119.00 per night, plus taxes

Deadline for Reservations: January 31, 2018

Interested in sponsoring or exhibiting?

Contact Carole Miller at
carole.miller@mdpha.com
or 443-583-8000



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- **\$100 Lifetime** processing fee—NO other charges or deductions.
- The **only way** to really know what we're about is to talk with us.

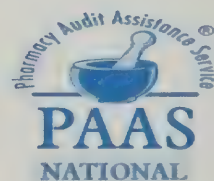
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The latest on provider status at the federal, state levels

By Rachel Balick, assistant editor, *Pharmacy Today*

APhA and its partners in the Patients' Access to Pharmacist Care Coalition (PAPCC) remain focused on efforts to advance the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 109) on Capitol Hill. While the exact future of the Affordable Care Act continues to evolve in Congress, APhA and PAPCC will continue to explore avenues to advance the provider status recognition bill and ensure that Medicare Part B beneficiaries in medically underserved communities have access to pharmacist-provided care. The bill is up to 206 cosponsors in the House and 43 cosponsors in the Senate.

Grassroots advocacy

Pharmacists across the country used Congress's August recess to push for provider status recognition by hosting elected officials to see the work they do for patients and their communities firsthand. Historically, August is when legislators return to their districts or states, providing pharmacists and their allies an opening to advocate and make personal connections with decision makers as the constituents directly affected by the proposed policy.

Did you host a pharmacy visit in August? Send copies of any photos you took during a site visit directly to your legislators and to APhA so we can recognize your advocacy efforts.

Stay on top of the latest news on federal provider status legislation and learn more about how to advocate for the issues that affect patients and pharmacists most by visiting www.pharmacistsprovidecare.com.

State action in MA and TN

Meanwhile, states are pursuing provider status recognition in their own ways. So far, 2017 has seen movement in Massachusetts, Indiana

(see page 4 in the August 2017 issue), and Tennessee.

Massachusetts. In June, the Massachusetts Senate and House of Representatives health care committee held a hearing on legislation that would expand the scope of practice for pharmacists in the state. Among those who testified on "An Act Recognizing Pharmacists as Healthcare Providers" (HB 1214/SB 1240) were the leadership of the Massachusetts Pharmacists Association (MPHA) and Massachusetts Independent Pharmacists Association (MIPA), pharmacists representing diverse practice settings, and physician supporters.

The bills would "increase access to care, optimize medication therapy, improve health outcomes, and minimize adverse drug reactions" and "allow clinical pharmacy programs to be sustainable and allow pharmacists to practice at the top of their license to provide comprehensive care as part of an integrated health care team," said MPHA president Alicia Mam daCunha, PharmD, AE-C, BCACP.

The bills' provisions would allow pharmacists with collaborative practice agreements to modify dosages of medications prescribed by the patient's physician for any diagnosis and administer drugs and biological products ordered by the supervising physician. In addition, if the legislation becomes law, pharmacists would gain the authority to furnish self-administered hormonal contraceptives and nicotine replacement products. Also, it would allow pharmacists to negotiate with health plans to provide medication therapy management (MTM) services.

Tennessee. The Volunteer State saw major provider status legislation take effect on July 1. "Pharmacists as Providers" (HB 405/SB 461) gives

States are pursuing provider status recognition in their own ways.

Tennessee pharmacists formal recognition as providers through managed health insurance issuers, including reimbursement and inclusion in medical networks, as providers of care.

The Tennessee Pharmacists Association (TPA) worked with legislators, managed health insurance issuers, and key pharmacy advocacy groups to introduce and pass the bill. "This legislation creates exciting new opportunities for pharmacists and also increases patient access to essential care and services," said Micah Cost, PharmD, MS, TPA executive director.

This landmark legislation provides a pathway for pharmacists who are acting within the scope of their license or certification under state law to be credentialed with managed health insurance issuers and enable them to participate, receive referrals, and be reimbursed for covered services or indemnification. It also creates a mechanism for pharmacists to participate as members of the larger health care team, resulting in increased communication, collaboration, and patient referrals, as appropriate, to physicians and other health care providers for further assessment, management, and treatment.

"Through state-based provider laws passed in Washington and Tennessee, state associations are building the framework for implementation of H.R. 592/S. 109 when it becomes law," Cost added. "These state-based provider laws showcase the important synergy between state and national pharmacists associations." ●

Fourth Quarter 2017: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1992

- For fiscal 1992, the total amount Medicaid spent on drugs in 1992 approached \$6.8 billion.
- National health care spending was \$854.1 billion or \$3287/person
- There were 75 accredited colleges of pharmacy (compared to 130 in 2015)

1967

- For fiscal year 1967, the total amount Medicaid spent on drugs exceeded \$182 million.
- National health care spending was \$51.6 billion or \$253/person

1942

- Marijuana was removed from the US Pharmacopeia in 1942. It had been included since 1854.
- Premarin first marketed by Ayerst.

1917

- Dean Rufus Lyman of the University of Nebraska calls for the formation of a national pharmacy honor society that is eventually realized with the founding of the Rho Chi Society.

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: www.aihp.org

In Case You Missed It

Reminder: Register with the Maryland PDMP

The deadline to register was July 1, 2017 -- but currently, only 58% of pharmacists have registered! If you have not done so, please register today.

You **must register** in the PDMP if you are a licensed pharmacist in Maryland, regardless of practice setting or dispensing role. Register at crisphealth.org.

Questions? Please contact the CRISP support team at (877) 852-7477 or support@crisphealth.org.



October 26

Public Board of Trustees Meeting — MPhA Headquarters, Columbia, MD

Visit MPhA Website for more details

November 16

Public Board of Trustees Meeting — MPhA Headquarters, Columbia, MD

December 14

Public Board of Trustees Meeting and Holiday Party — MPhA Headquarters, Columbia, MD

January 25

Public Board of Trustees Meeting — MPhA Headquarters, Columbia, MD

February 18

Mid-Year Meeting — DoubleTree by Hilton, Annapolis, MD

February 20

Legislative Day — St. John's College, Annapolis, MD

Lack of provider status for pharmacists is barrier to pain relief for patients

By Sonya Collins, MA, MFA, contributing writer, *Pharmacy Today*

The patient, "Neil," was in the final stages of pancreatic cancer. His only wish was to be able to spend his last days with his family, preferably at home. But he was in too much pain to move from his hospital bed, much less interact with family. Opioids were not much use to him—the quantity needed to numb the pain rendered him incapable of communicating with his wife and children.

That's when Jessica Geiger-Hayes, PharmD, clinical pharmacist on the



Jessica Geiger-Hayes

palliative care team at Ohio Health Riverside Methodist Hospital, intervened. As a palliative care pharmacist, Geiger-Hayes's focus is to help relieve the painful

symptoms of end-stage, terminal illnesses. She offers solutions to patients and their families and also physicians, who often feel they've used all the tools in their toolbox to treat their patients' pain. She educates patients and providers on medication options, recommends medication and dose changes, and follows up with patients to ensure the regimen is having the intended effect.

"I help the team get very creative with therapy, and that doesn't necessarily mean using opioids," said Geiger-Hayes.

Geiger-Hayes worked with the physician and suggested they treat

The patient cried. The nurses fought back tears. No one could do anything to relieve the patient's pain.

Neil with ketamine—a medication the physician hadn't considered at first and the patient knew little about. The physician was open to the suggestion, and both the patient and the physician accepted Geiger-Hayes's recommendation.

"After two doses, he got out of bed and walked down the hall," Geiger-Hayes said. "Shortly after that, he went home and was able to pass away comfortably and peacefully at home with his family rather than in a hospital."

Geiger-Hayes wishes it were always that easy to help her patients get relief for their pain. But at times when the pharmacist cannot reach the physician immediately, patients and their families suffer unnecessarily. Though physicians routinely seek Geiger-Hayes's advice and frequently accept her recommendations, she is not authorized to change or initiate medication. Pharmacists, unlike other health professionals, are not recognized by CMS as health care providers. The lack of recognition helps sustain antiquated pharmacy practice acts in many states, where pharmacists' scope of practice lags far behind the current scope of their training and expertise. As a result, pharmacists cannot provide patients

the level of care that aligns with their expertise, and it's patients who suffer the consequences of the restrictions placed on pharmacists.

Geiger-Hayes recalls a patient writhing with pain in her hospital bed. The patient's husband sat by her bedside, crying helplessly. The patient cried. The nurses fought back tears. No one could do anything to relieve the patient's pain. Geiger-Hayes had several ideas, which she had discussed with the patient and her family, about how to relieve the pain. But she couldn't reach the doctor—the only health care provider who had the authority to order a change in medication.

"My hands are tied. I cannot give a nurse an order to administer an extra dose of any medication. I couldn't adjust anything. So, I just had to sit there with everybody else and wait for someone to call me back to get an order to treat this person's pain," Geiger-Hayes said. "That's no way to treat a patient."

Pharmacists are often considered the most accessible, but also the most under-utilized, providers in the health care system. But neither patients nor pharmacists' health care colleagues can take full advantage of pharmacists without laws to facilitate access.

"That's the biggest barrier," Geiger-Hayes said. "I'm on a team of providers that trust me. Patients and their families trust me. But, legally, there is only so much that I can do." ●

DISCLOSURE

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Mineralocorticoid Receptor Antagonists: The Wonder Class

A Review of Cardiovascular Indications and Barriers to Use

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Learning Objectives

At the conclusion of this activity, through literature and case study, participants will be able to:

1. Distinguish the differences in mechanism, pharmacokinetics, cost efficacy, and tolerability profiles of the mineralocorticoid receptor antagonists (MRAs), spironolactone and eplerenone
2. Identify relationships between the mechanisms of action of MRAs and cardiovascular disease pathophysiology
3. Dissect barriers to the use of MRAs across a number of special populations
4. Apply evidence-based literature to define the role of MRAs in heart failure, acute coronary syndrome, or resistant hypertension given a patient case

Key Words

Spironolactone | Eplerenone | Cardiovascular disease

Introduction

Mineralocorticoid receptor antagonists (MRAs) are arguably one of the most underutilized medication classes despite sound evidence supporting their use across a spectrum of cardiovascular (CV) diseases, often due to concerns for adverse events (AEs).¹⁻³ This article describes current evidence on the use of MRAs in the treatment of heart failure (HF), myocardial infarction (MI), and resistant hypertension. Considerations regarding blood pressure, potassium, and renal effects are also included, as these play key roles in precluding MRA selection.

MRAs in Cardiovascular Disease

Heart Failure with Reduced Ejection Fraction

The role of MRAs is most recognized in the treatment of heart failure

with reduced ejection fraction (HFrEF). These agents, which include spironolactone and eplerenone, are recommended in the 2013 American College of Cardiology Foundation/American Heart Association heart failure guideline for patients with HFrEF with mild to severe symptoms (i.e., New York Heart Association [NYHA] Class II-IV symptoms). An explanation of NYHA classifications is listed in Table 1. For patients with NYHA Class II symptoms, MRAs are recommended for those with an elevated brain natriuretic peptide (BNP) or previous CV hospitalization.⁴ These recommendations are based on the results of two randomized, controlled trials: the Randomized Aldactone Evaluation Study (RALES) and the Eplerenone in Mild Patients Hospitalization and Survival Study in Heart Failure (EMPHASIS-HF), which evaluated the efficacy and safety of spironolactone and eplerenone, respectively.

In RALES, patients with NYHA Class III or IV symptoms and left ventricular ejection fractions (LVEF) <35% receiving angiotensin converting enzyme inhibitors (ACEi) and diuretics were randomized to spironolactone at a dose of 12.5 to 25 mg daily or placebo. This trial was terminated early due to the benefits of therapy. The use of spironolactone decreased the risk of death (45.9% with placebo vs. 34.4% with spironolactone, hazard ratio [HR], 0.70 [95% confidence interval (CI), 0.60-0.82], $p < 0.001$) with a number needed to treat (NNT) of 9 over 24 months. The use of spironolactone was associated with a 35% reduction in HF hospitalization ($p < 0.001$) as well as a significant improvement in NYHA functional class.⁵ Over ten years later, EMPHASIS-HF was published, which was not only important for determining a "class-effect" for MRAs in HFrEF, but established the utility of these agents for patients with

TABLE 1:
New York Heart Association Functional Classifications⁴

NHYA Class	Definition
I	No limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitations, dyspnea
II	Slight limitation of physical activity; comfortable at rest; ordinary physical activity results in fatigue, palpitations, dyspnea
III	Marked limitation of physical activity; comfortable at rest; less than ordinary activity causes fatigue, palpitations, or dyspnea.
IV	Unable to carry on any physical activity without discomfort; symptoms of heart failure at rest

*Functional class is related to symptoms and therefore can improve or worsen throughout course of disease

less severe disease already receiving optimal guideline-directed medical therapy. In RALES, only 10.5% of patients were on beta-blockers, leading many critics to argue that the benefits of spironolactone were due to suboptimal guideline-directed medical therapy. EMPHASIS-HF enrolled patients with LVEF <35% and NYHA class II symptoms, 88% of which were on beta-blocker therapy, to evaluate the efficacy of eplerenone 25 to 50 mg daily. Despite better baseline therapy, the trial was also terminated early due to a discernable decrease in the composite primary outcome of CV death and hospitalization for HF (HR 0.63 [95% CI, 0.54-0.74], $p < 0.001$).⁶ The NNT to reduce the composite endpoint was 19 per year of follow-up.

Heart Failure with Preserved Ejection Fraction

Patients with HF with preserved ejection fraction (HFpEF) are arguably the population where MRAs are most underutilized. The limited use of MRAs in HFpEF is likely due to the results of the Spironolactone for Heart Failure with Preserved Ejection Fraction (TOPCAT) trial, which showed no difference in the composite primary outcome of CV death, aborted cardiac arrest, or hospitalization for HF among patients with LVEF $\geq 45\%$ receiving spironolactone 15 to 45 mg daily versus placebo. Other than a preserved LVEF, patients in this trial were included if they had a hospitalization within the

previous 12 months or elevated BNP within 60 days; the majority of patients were NYHA Class II or III. Approximately one-half of the patients enrolled were from the Americas, whereas the other half were from Russia and Georgia. Although no reduction in mortality was seen, there was a significant decrease in hospitalizations with spironolactone (HR 0.83, [95% CI, 0.69-0.99], $p = 0.04$), with a NNT of 45 over a 3.3 year period. The population studied in the Americas had a much higher rate of the primary outcome (27.3%) in the spironolactone group, compared to a rate of only 9.3% seen with spironolactone in Russia and Georgia. This translated to a significant decrease in the treatment group in the Americas (27.3% vs. 31.8% with placebo, $p = 0.026$), as opposed to no difference seen in Russia and Georgia (9.3% vs. 8.4%, $p = 0.576$).⁷ A likely reason for this is differences in the standards and structure of the healthcare systems in these countries. Patients in the Americas are more likely to be hospitalized for less life-threatening ailments than those in Russia or Georgia; therefore, it would be difficult to detect a difference given such low event rates in the latter population.

Biorepository data supports the notion that other regional differences may have also impacted the results of TOPCAT. Among those enrolled in the study, 360 provided serum samples. Canrenone, the active metabolite of spironolactone,

was undetectable in 30% of participants from Russia versus 3% of those from the United States and Canada ($p < 0.001$), suggesting that the results from Russia do not reflect therapeutic concentrations of spironolactone.⁸ There have since been trials confirming the improvement in symptoms with MRA therapy in HFpEF.

Recently, the Spironolactone in myocardial dysfunction with reduced exercise capacity (STRUCTURE) trial suggested an improvement in exercise capacity with spironolactone in patients with HFpEF.⁹ In a specialty saturated with large, randomized, controlled trials and impactful outcomes, we often forget that mortality should not be the only criteria for determining which agents should be initiated in those with CV disease. In patients with HFpEF, reducing both symptoms and the risk of hospitalizations is likely the best available option, and thus MRAs should be considered in this population. Furthermore, it is possible that the relatively short duration of the TOPCAT study (3.3 years) may be insufficient to detect an effect on mortality rates as patients with HFpEF have been shown to be at an increased risk for sudden cardiac death in studies up to 5 years.¹⁰⁻¹¹

Myocardial Infarction

MRAs are also recommended for patients who are post-MI with

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reduced ejection fraction and diabetes mellitus or symptoms of HF.¹² This is based on the results of the Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival (EPHESUS) study, which randomized the aforementioned population to eplerenone (25 mg daily titrated to max 50 mg daily after 4 weeks) or placebo. Use of eplerenone was associated with a reduction in all-cause death (HR 0.85, [95% CI, 0.75-0.96], $p=0.008$) and a composite of CV death and CV hospitalization (HR 0.87, [95% CI, 0.79-0.95], $p=0.002$).¹³ Data for MRAs is not as strong, however, for patients post-MI without HF. The recently published Aldosterone Lethal Effects Blockade in Acute Myocardial Infarction Treated With or Without Reperfusion to Improve Outcome and Survival at Six Months' Follow-Up (ALBATROSS) study found no difference in outcomes with spironolactone therapy within 12-24 hours of MI versus standard treatment in post-MI in this population, which included 7.2% of patients with a diagnosis of HF upon presentation and a mean LVEF of 50%.¹⁴ There was a reduction in mortality in a subgroup of patients who presented with a ST-elevation MI (STEMI) (HR 0.20, [95% CI, 0.06-0.69], $p=0.0044$) with early MRA therapy. The Early Mineralocorticoid Receptor Antagonist Treatment to Reduce Myocardial Infarct Size (MINIMISE STEMI) study evaluating the use of MRA therapy in STEMI patients with preserved EF post-MI has been completed, but results have yet to be published.¹⁵

Resistant Hypertension

The efficacy of MRAs in resistant hypertension is unsurprising considering hyperaldosteronism is one of the most common causes of resistance.¹⁶ Resistant hypertension is defined as blood pressure (BP) not at goal on three antihypertensives at

optimal doses, including a diuretic, or BP that is controlled on four or more agents. The 2014 Eighth Joint National Committee Hypertension Guidelines recommend MRAs as 4th line therapy in patients not controlled on maximally tolerated ACEi or angiotensin receptor blocker (ARB), calcium channel blocker (CCB), and thiazide-type diuretic.¹⁷ Multiple trials evaluating the safety and efficacy of spironolactone in this population have been published over the last several years.

In 2003, Nishizaka et al. described the use of spironolactone 25-50 mg as add-on therapy, demonstrating a mean BP lowering of 21/10 mmHg after 6 weeks. Patients enrolled in this study were not at their BP goal despite receiving three antihypertensives, including an ACEi/ARB and diuretic, although the diuretic type was never specified.¹⁸ The Anglo-Scandinavian Cardiac Outcomes Trial-Blood Pressure Lowering Arm (ASCOT-BPLA) trial later evaluated the effects of various antihypertensives on CV events in patients aged 40-79 with hypertension and at least three other CV risk factors.¹⁹ Although the major arms of this trial compared amlodipine (with the addition of an ACEi, as needed) to atenolol (with the addition of bendroflumethiazide, as needed), a post-hoc analysis demonstrated similar BP reductions in patients who received spironolactone 25 mg, as a fourth-line agent, to those previously published in the Nishizaka et al. trial.²⁰

The Addition of Spironolactone in Patients With Resistant Arterial Hypertension (ASPIRANT) trial included patients with treatment resistant hypertension who were receiving an ACEi/ARB, CCB, and diuretics, the majority of which were thiazide-like. Despite a treatment-resistant patient population, there was a statistically significant decrease in mean 24-hour systolic

BP (SBP) of 6.6 mmHg ($p=0.004$) with the addition of spironolactone 25 mg compared to placebo.²¹ This finding was supported by the recent Spironolactone Versus Placebo, Bisoprolol, and Doxazosin to Determine the Optimal Treatment for Drug-resistant Hypertension (PATHWAY-2) study, a randomized, double-blind, crossover trial, in which a similar patient population rotated through 12 weeks of spironolactone 25-50 mg, bisoprolol, doxazosin, and placebo plus baseline anti-hypertensive medications. Spironolactone was associated with an average decrease in SBP of approximately 4 mmHg more than doxazosin and bisoprolol and over 8 mmHg when compared to placebo ($p<0.001$ for all comparisons). There was no difference in BP-lowering between the other agents and placebo.²²

Barriers to Therapy: Appropriate Patient Selection and Monitoring

Hypotension

Although many benefits with MRAs have been demonstrated in the literature, apprehension surrounding AEs often preclude their use. Prescribers are frequently hesitant to start spironolactone for indications other than hypertension in patients with borderline "low" pressures due to concerns for hypotension. However, a Cochrane review in 2010 found similar BP-lowering in patients with primary essential hypertension with spironolactone versus placebo.²³ As discussed throughout this review, there are many non-hypertensive patients with indications for MRAs. This is especially true in HFrEF, a population in which normotension at baseline often occurs due to reduced cardiac output (CO). In fact, a decrease in systemic vascular resistance can actually increase CO when MRAs are initiated, leaving

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Patient Case

JP is a 66-year-old African American male who presents to the cardiomyopathy clinic for routine follow-up after recent HF hospitalization. Patient reports compliance to medications. He currently sleeps on 3 pillows at night, but denies paroxysmal nocturnal dyspnea, being awakened by inability to breathe. Patient endorses lower leg swelling. He is able to perform simple chores around the house without development of dyspnea on exertion and walks 3 blocks before experiencing shortness of breath. Denies chest or leg pain. Patient does not have insurance and is concerned about the cost of his medications.

Past Medical History	Current Medications
DM CKD II GERD ICM (LVEF 30%) STEMI s/p DES x 1 to LAD (2014)	Aspirin 81 mg daily Atorvastatin 80 mg daily Ranitidine 150 mg BID Furosemide 40 mg daily Metoprolol succinate 200 mg daily Metformin 1000 mg BID Lisinopril 20 mg daily

Vitals

T: 97.9 | HR: 78 | RR: 18 | BP: 108/66 mm Hg
Weight: 84 kg | Height: 70 inches

135	100	32	126
4.7	22	1.76	

1. Based on current literature, the addition of spironolactone has the following clinical implication(s):

- Decreased mortality in HFrEF
- Reduced hospitalizations
- Reduced risk of diabetic nephropathy
- All of the above

Answer: D. As discussed in the article, MRAs have a variety of indications, due to studies across various disease states that have shown an improvement in clinical outcomes. RALES and EMPHASIS-HF demonstrated a decrease in mortality and hospitalizations in HFrEF with the addition of spironolactone and eplerenone, respectively (Answer A&B are correct). Additionally, it is hypothesized that ACEi and ARB therapy may not completely inhibit aldosterone release; studies have shown that the addition of MRA therapy in patients with diabetes could reduce the incidence of albuminuria (Answer C is correct). Therefore, the addition of an MRA in JP could have all of the above implications (Answer D is correct).

2. Which of the following is true in terms of initiation and/or monitoring for JP if selected for MRA therapy?

- No monitoring is necessary. JP's serum creatinine is less than 2.5 mg/dL at initiation, therefore he is not at risk for adverse effects.

- JP's serum creatinine and potassium should be monitored within one week of initiation.
- Concomitant use of lisinopril decreases JP's risk of hyperkalemia, therefore no additional monitoring is necessary.
- JP's blood pressure is already too low to initiate MRA therapy.

Answer: B. Although MRA therapy has demonstrated improved outcome across several indications, appropriate patient selection and monitoring are prudent for safe use of these agents. Baseline serum creatinine and serum potassium should be obtained to evaluate for appropriateness of therapy. Regardless of whether laboratory abnormalities exist at baseline, these labs should be rechecked within one week of MRA initiation to assess for changes (Answer A is incorrect, Answer B is correct). Although the concomitant use of loop diuretics may decrease the risk of hyperkalemia, ACE inhibitors increase this risk; careful monitoring is recommended when changes to concomitant medications are made (Answer C is incorrect). Patients with HFrEF often have lower baseline systolic pressures due to a reduction in cardiac output. Despite the efficacy of MRA therapy in resistant hypertension, patients with HFrEF may see unchanged or increased blood pressures due to the afterload reduction achieved by this class. MRA therapy should not be withheld in HFrEF due to blood pressures that would be considered low in a patient with normal systolic function (Answer D is incorrect).

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overall mean arterial pressure unchanged. However, this does not necessarily occur in patients with HFpEF, where cardiac filling is more dependent on preload and can be affected by a decrease in sodium and water retention. As such, MRAs remain an option in normotensive patients with other indications for aldosterone antagonism, especially in HFrEF. Furthermore, in patients with HFrEF and blood pressures that would normally be considered hypotensive, MRA therapy should still be considered, unless low blood pressures are symptomatic. MRA therapy should be utilized more conservatively in patients with preserved LVEF, although no specific blood pressure thresholds have been defined. Patients who are placed on MRA therapy, in particular those without conditions associated

with volume overload, should be counseled regarding the risks of dehydration, especially in the setting of diarrhea and acute illness, as these can contribute to the risk of hypotension.

Hyperkalemia

Hyperkalemia is a major AE that prevents the use of MRAs in many patients. In the RALES and EPHESUS trials, potassium increased by an average of 0.3 mEq/L after one year of treatment. In RALES, there was no difference in the incidence of serious hyperkalemia (defined as ≥ 6 mEq/L) in the spironolactone group compared to placebo (2% vs. 1%, $p=0.42$)⁵ whereas in EPHESUS, eplerenone did increase the risk of serious hyperkalemia (5.5% vs. 3.9%, $p=0.002$).⁶ Impaired renal function was found to be a predictor

of this effect, with increased incidence seen in the strata of patients with creatinine clearance < 50 mL/min.⁶ A population-based time-series of 1.3 million patients in Canada evaluated the incidence of hyperkalemia with spironolactone in a real world setting. A statistically significant increase in the spironolactone prescription rate, hospitalizations for hyperkalemia (2.4 per 1000 patients to 11.0 per 1000 patients, $p<0.001$), and hyperkalemia-associated mortality (0.3 per 1000 patients to 2.0 per 1000 patients, $p<0.001$) were seen after the publication of RALES. This was in addition to no significant decreases in the rates of HF readmissions or all-cause mortality, suggesting that the risks and benefits of this class may differ in a real-world setting.²⁴

Patient Case Continued

Spironolactone 25 mg daily is added to JP's regimen. Patient does well on this medication and presents to clinic for a routine follow-up visit 4 years later. JP has no complaints, stating that his shortness of breath and dyspnea on exertion have been stable since previous visits.

Vitals

T: 98.6 | HR: 74 | RR: 16 | BP: 112/68 mm Hg
Weight: 82 kg

139	98	21	135
5.2	22	1.90	

3. Based on current literature, the addition of spironolactone has the following clinical implication(s):

- Discontinue spironolactone.
- Decrease spironolactone to 12.5 mg daily
- Change spironolactone to eplerenone
- Discontinue lisinopril

Answer: B. Potassium increases following the initiation of MRA therapy are not unexpected. As with any medication, it is important to consider the risks versus benefits before continuing or discontinuing therapy. Continuing therapy has the potential to decrease mortality and hospitalizations for HFrEF, therefore MRA therapy should be continued, if

possible (Answer A is incorrect). Although the incidence of sexual side effects can be mitigated by switching spironolactone to eplerenone, both agents are associated with an increase in the risk of hyperkalemia (Answer C is incorrect). Concomitant medications that can increase the risk of hyperkalemia should be taken under consideration; although lisinopril can contribute to elevations in serum potassium, ACE inhibitors are considered a backbone of therapy in HFrEF and also reduced the risk of diabetic nephropathy. Lisinopril should be continued, if possible (Answer D is incorrect). In patients with a serum K⁺ between 5.1-5.4, we recommend decreasing the dose of MRA therapy by 50%, if possible (Answer B is correct) and rechecking labs within one week.

TABLE 2:
Recommendations for initial and maintenance dosing of MRAs from
the American College of Cardiology Foundation/American Heart Association⁴

	Eplerenone			Spironolactone		
eGFR (ml/min/1.73 m ²)	≥ 50	30 to 49	< 30	≥ 50	30 to 49	< 30
Initial dose (if K+ ≤ 5 mEq/L)	25 mg qday	25 mg every other day	Use not recommended	12.5 to 25 mg qday	12.5 mg qday or every other day	Use not recommended
Maintenance dose (if K+ ≤ 5 mEq/L after 4 weeks of therapy)	50 mg qday	25 mg qday	N/A	25 mg qday or BID	12.5 to 25 mg qday	N/A
eGFR, estimated glomerular filtration rate Information adapted from 2013 American College of Cardiology Foundation/American Heart Association Heart Failure Guideline.						

Patients in clinical trials are rigorously followed according to strict protocols for AEs, whereas in clinical practice patients are less closely monitored. The results of this publication strengthen the idea that combination drug therapy may simultaneously improve clinical outcomes and enhance the risk of potassium-related AEs; therefore, an appropriate balance of benefit and risk depends heavily on careful patient selection and adequate surveillance of serum potassium concentrations and renal function. Dosing and monitoring recommendations based on patient-specific factors are provided in Tables 2 and 3. Additionally, conditions that may predispose patients to hyperkalemia (e.g., renal dysfunction) and concomitant medications (e.g., ACEi/ARB) should be taken into consideration. It is imperative that other sources of potassium be identified and eliminated to reduce this risk of hyperkalemia in patients receiving MRAs. Patients should be counseled regarding avoidance of potassium-containing salt substitutes and potassium supplements should typically be discontinued.

Special Populations: Renal Dysfunction

Exclusion criteria in various trials evaluating MRAs often limit its use

in patients with renal dysfunction. However, it is widely accepted that CV events are the leading cause of death in patients with end-stage renal disease (ESRD).²⁵ In this patient population, aldosterone levels increase paradoxically with glomerular filtration rate. For this reason, the mechanism of MRAs render the class an attractive option in these patients. Patients with ESRD are also at an increased risk for hyperkalemia, which is another concern for the addition of spironolactone. However, small studies have shown a reduction in CV mortality and hospitalization with spironolactone in patients with ESRD on hemodialysis without an increase in hyperkalemia rates.²⁶⁻²⁷ It is important to note, though, that most of these studies were performed in anuric patients, who no longer have the ability to retain potassium via renal mechanisms. Consequently, the risk of hyperkalemia is higher in oliguric patients, especially between hemodialysis sessions. Table 2 outlines the recommendations for initial and maintenance dosing of MRAs from the American College of Cardiology Foundation/American Heart Association. Table 3 includes our dosing and monitoring recommendations based on all available literature, including special considerations for use in renal

dysfunction and elevated potassium levels. Currently, the ALDosterone Antagonist Chronic HEModialysis Interventional Survival Trial (ALCHEMIST), is currently recruiting patients and will further elucidate the efficacy and safety of MRAs in patients with ESRD in a randomized, controlled fashion.²⁸

Another potential area of benefit for spironolactone is to reduce the risk of diabetic nephropathy. The standard of care for renal preservation in diabetic patients is the addition of an ACEi or ARB.²⁹ However, it has been hypothesized that ACEi and ARBs are not completely effective at suppressing aldosterone release in patients with HF or diabetes.³⁰ This is a result of aldosterone release through mechanisms other than angiotensin II-mediated release, a phenomenon referred to as aldosterone escape syndrome. Aside from the subsequent increase in sodium and water retention, aldosterone escape syndrome can also contribute to renal dysfunction. There are several studies to suggest that even in patients on maximally tolerated doses of ACEi or ARBs, the addition of spironolactone at 25 mg per day, or eplerenone 50 to 100 mg daily can significantly reduce albuminuria.³¹ Therefore, patients with diabetes are another

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TABLE 3:
MRA Author Practice Recommendations^{25-27,36-39}

	Dosing	Monitoring	Additional Considerations for Adjustment
Spironolactone	12.5 mg to 25 mg daily	SCr and K ⁺ at baseline, within 1 week of therapy, after 4 weeks, then every 3 to 6 months*	Renal dysfunction: CrCl < 30 mL/min including ESRD HD (oliguric): initiate at low doses; use with caution/monitor closely ESRD HD (anuric): no initial adjustment required, monitor closely
Eplerenone	25 to 50 mg daily		Hyperkalemia: K ⁺ ≥ 5.5 mEq/L: discontinue therapy K ⁺ 5.1-5.4: decrease dose by 50%

CrCl, creatinine clearance; ESRD, end-stage renal disease; HD, hemodialysis

*Monitoring should also be included with dose adjustments or the addition of concomitant medication that affect potassium and/or renal function

population that may benefit from the addition of MRAs. Despite the potential benefits of this therapy, patients with DM and renal dysfunction are at increased risk for hyperkalemia and should be monitored closely.

Special Populations: Black Patients

It is now widely recognized that African American patients may not respond equally to all medication classes. This has been demonstrated in hypertension studies, where the effects of ACE/ARB therapy are limited compared to white populations.³² Current hypertension guidelines have specific recommendations for the use of other classes of drugs, such as CCBs and thiazide diuretics as first line agents in this population.¹⁷ The hypothesized mechanism for this lack of response is due to African Americans having a lower renin profile and a higher sensitivity to sodium.³³ Incidentally, a sub-analysis of the resistant hypertension trial by Nishizaka et al. found that spironolactone was most effective in patients with lower renin levels.¹⁸ The African American population in general is at an increased risk for many cardiovascular risk factors, such as diabetes and chronic

kidney disease, and therefore may benefit from attenuation of aldosterone production.³³ Studies have shown comparable blood pressure lowering with MRAs in black patients compared to white patients, as well as increased efficacy of MRAs compared to the ARB losartan in black patients.³⁴ However, in a sub-analysis of African American patients in RALES, there was less hyperkalemia and more hypokalemia associated with spironolactone in the African American populations, as well as a smaller reduction the combined end point of death or hospitalization for HF, suggesting less efficacy in this population.⁵

Spironolactone vs. Eplerenone

Aside from hyperkalemia and renal dysfunction, spironolactone increases the risk of sexual side effects including menstrual irregularities and gynecomastia.³⁵ This is a result of the nonselectivity of spironolactone for the mineralocorticoid receptor, with additional effects on androgen and progesterone receptors. This nonselectivity, however, is also responsible for spironolactone's efficacy in a wide array of non-cardiac indications, including

acne and hirsutism. Conversely, eplerenone, exhibits increased selectivity for the mineralocorticoid receptor and can be utilized in patients who experience sexual AEs with spironolactone. Additionally, eplerenone is metabolized by CYP3A4. As such, the risk AEs, including hyperkalemia, may be increased as a result of concomitant CYP3A4 inhibition. Patients on eplerenone should be monitored for drug-drug interactions. Historically, cost has been a major limiting factor for eplerenone, but the cost differential between the two agents has narrowed over the past few years.

Conclusion

Despite the overwhelming evidence to suggest their use in the CV disease realm, MRAs remain an underutilized drug class, likely due to the AEs associated with these agents. Despite the effects of MRAs on potassium, BP and renal function, the opportunity to improve outcomes with use of MRAs without compromising safety, especially in HF patients, is tightly coupled to appropriate patient selection, individualized drug dosing, and attentive monitoring in accordance with established guidelines.

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The authors have no financial disclosures to report.

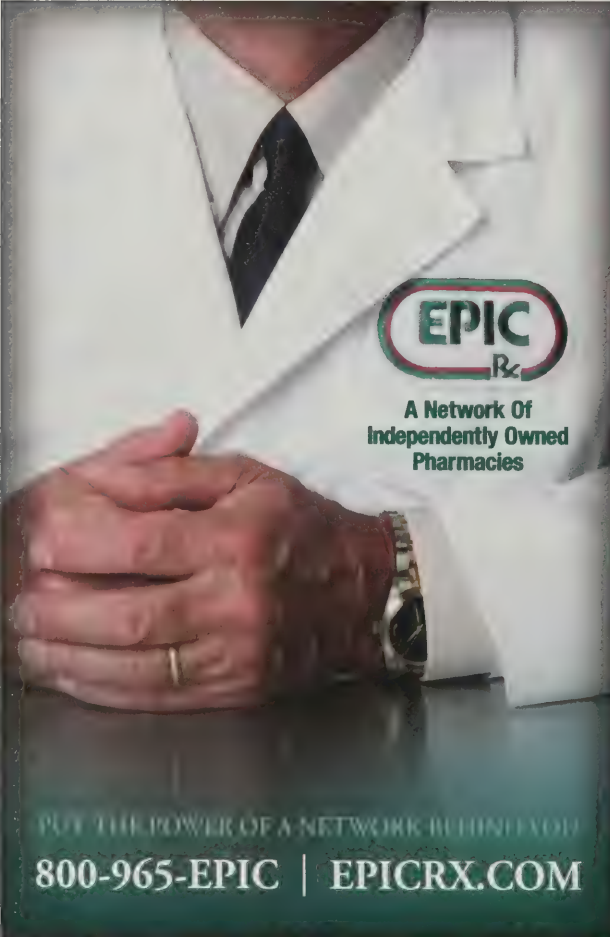
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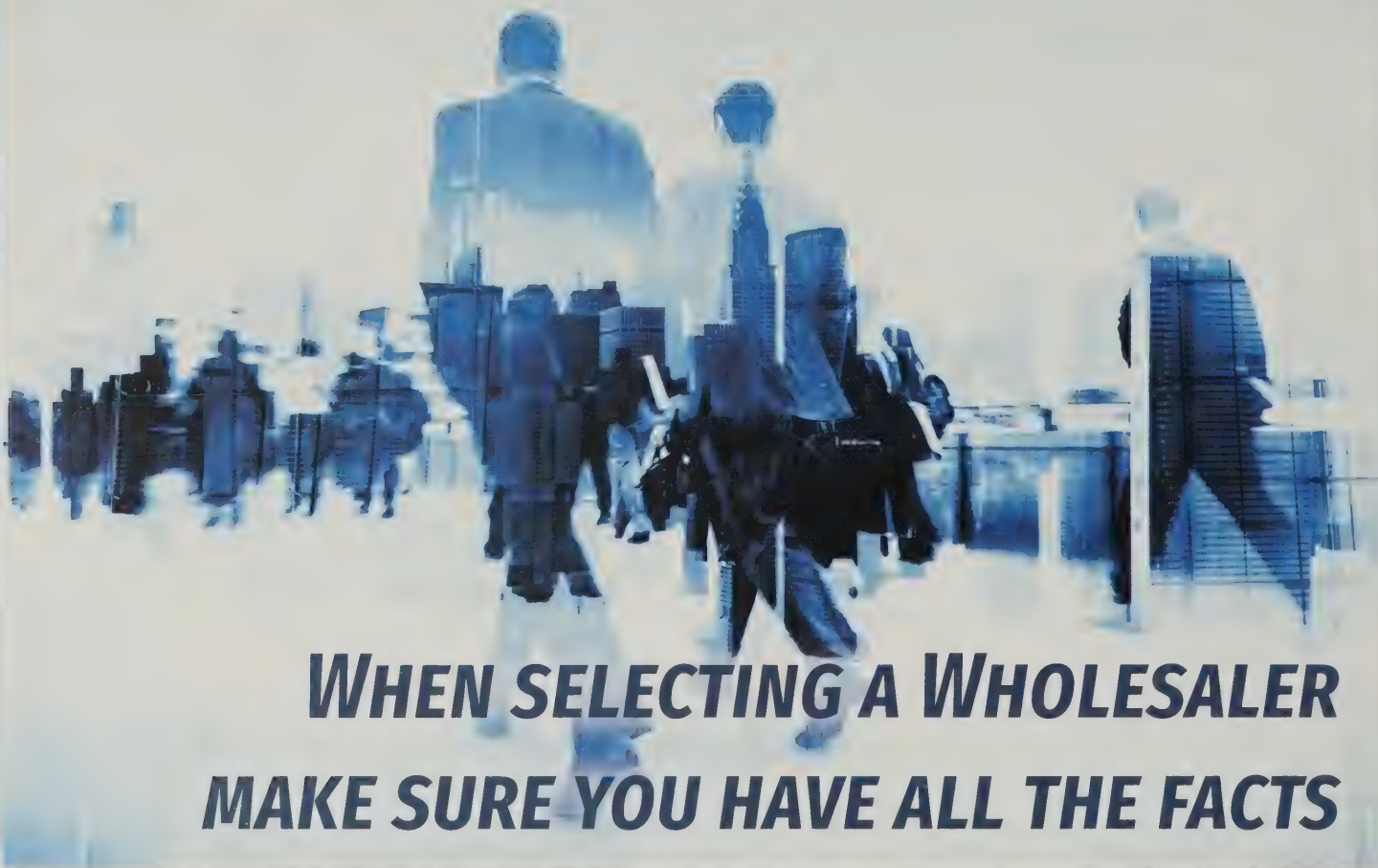
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Lixisenatide (Adlyxin®); New Drug Update

By: Amber R Benitez, Pharm.D., Candidate, University of Maryland Eastern Shore School of Pharmacy; and Matthew D. Balish, MS, PharmD, RPh. Pharmacist, Apple Discount Strugs, Salisbury MD

Lixisenatide (Adlyxin®) was approved by the Food and Drug Administration on July 28, 2016 for the treatment of type two diabetes as an adjunct to diet and exercise.¹

Lixisenatide is administered subcutaneously in the abdomen, thigh, or upper arm. It is dosed as 10 mcg once daily for the first 14 days and increased to the maintenance dose of 20 mcg once daily on day 15. Lixisenatide is given within 1 hour before the first meal of the day. As with other GLP-1 agonists there is no need for dose adjustment for hepatic disease. For patients with mild (GFR 60-89ml/min) to moderate (GFR 30-60 ml/min) renal impairment no dose adjustment is necessary but close monitoring is recommended. Caution with mild and moderate renal impairment is recommended due to the higher incidence of hypoglycemia, nausea, vomiting, and dehydration which can cause worsening of renal function. Since there is no data for patients with ESRD (GFR <15 ml/min) or on dialysis, treatment with lixisenatide is not recommended.^{1,2}

Lixisenatide proposed mechanism of action is glucagon-like peptide-1 (GLP-1) receptor agonist. It mimics the action of GLP-1 by increasing the incretin effect in patients with type 2 diabetes, stimulating the release of glucose-dependent insulin, decreasing glucagon secretion, and slowing gastric emptying. Common side effects include nausea, vomiting, headache, diarrhea, dizziness, injection site reactions and hypoglycemia. Pancreatitis is an infrequent adverse effect, which has been reported in post-marketing surveillance for all marketed GLP-1 receptor agonists.^{2,5} Use of lixisenatide in patients under 18 is not recommended. There is limited

data for patients over 65 from phase 2 and 3 clinical studies. Due to the higher incidence of hypoglycemia in the elderly population, data suggest use with caution. Since lixisenatide delays gastric emptying, it is important to take caution when taking oral contraceptives as it may decrease their effectiveness. It is recommended to take oral contraceptives one hour prior to or 11 hours following administration of lixisenatide²

Two clinical trials have shown the safety and efficacy of lixisenatide. The first study GetGoal-M was a 24-week placebo control study in type 2 diabetics with inadequate control on metformin. Study participants had HbA1C between 7-10%. At 24 weeks, patients with lixisenatide showed improved glycemic control, good post prandial effect, and few side effects compared to metformin and placebo. The second study, GetGoal-X, was a non-inferiority comparison of lixisenatide administered once-daily compared to exenatide administered twice-daily with patients who were inadequately controlled on metformin. Results showed that HbA1c reduction at 24 weeks was non-inferior. Lixisenatide (once daily) is comparable to exenatide (twice a day) in weight reduction, lower, hypoglycemic effect and better adherence. The main adverse event in both studies was gastrointestinal upset.^{3,4}

With the release of lixisenatide (Adlyxin & Lyxumia (in Europe) ®) there are now five products on the market in the class. The other drugs in the class include dulaglutide (Trulicity®), albiglutide (Tanzeum®), liraglutide (Victoza & Saxenda®) and exenatide (Byetta & Bydureon®). There are several clinical situations in

which patients with type 2 diabetes may benefit from treatment with a GLP-1 receptor agonist. This includes patients who are taking metformin, a sulfonylurea, or a thiazolidinedione (alone or in combination) but are not at their glycemic goal, as well as patients with an A1C of 7-9%. It is important to realize that a small percentage of patients experience no reduction or a minimal reduction in their blood glucose with a GLP-1 receptor agonist. With adverse events a frequent reason for poor adherence, inquiring about medication difficulties such as adverse events at all follow-up appointments is helpful and provides an opportunity to find solutions that are acceptable to patients. It is most helpful to discuss how to deal with common adverse events with patients at the time of therapy initiation.

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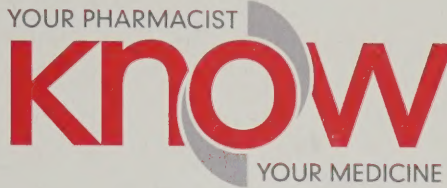
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As we celebrate American Pharmacists Month (October) and National Pharmacy Technician Day (third Tuesday in October) we recognize the work you do across practice settings that impacts Marylanders. You are not only the medication experts, but also the connectors on the healthcare team. You are working to address specific healthcare needs and larger public health issues in Maryland.

This is an opportunity to give thanks. Pharmacists continue to be ranked among the most honest and ethical professionals in the US. It is because you are not just a friendly face in the neighborhood, but you are also engaged in innovative programs to address the opioid epidemic, medication safety, immunization gaps, emergency preparedness and the list goes on and on. In some cases, you are also a business owner. It doesn't matter if you are seeing patients daily, working in a lab or educating the next generation. You are making a difference!

So many of you give your time and resources to work with MPhA and our national associations to educate elected leaders about the profession and the greater role you can play in improving patient outcomes while reducing overall healthcare costs. Staying true to the Oath of

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As your President Cherokee Layson-Wolf demonstrated in her President's Message, your leadership is poised and ready to advance MPhA as an organization by tackling tough issues. Support these efforts by renewing your membership and following our progress via social media at @amdpharmacist (Twitter) or on Facebook.

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Aliyah N. Horton, CAE
Executive Director



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